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(54) Title: TISSUE IMAGING SYSTEM AND METHOD FOR TISSUE IMAGING

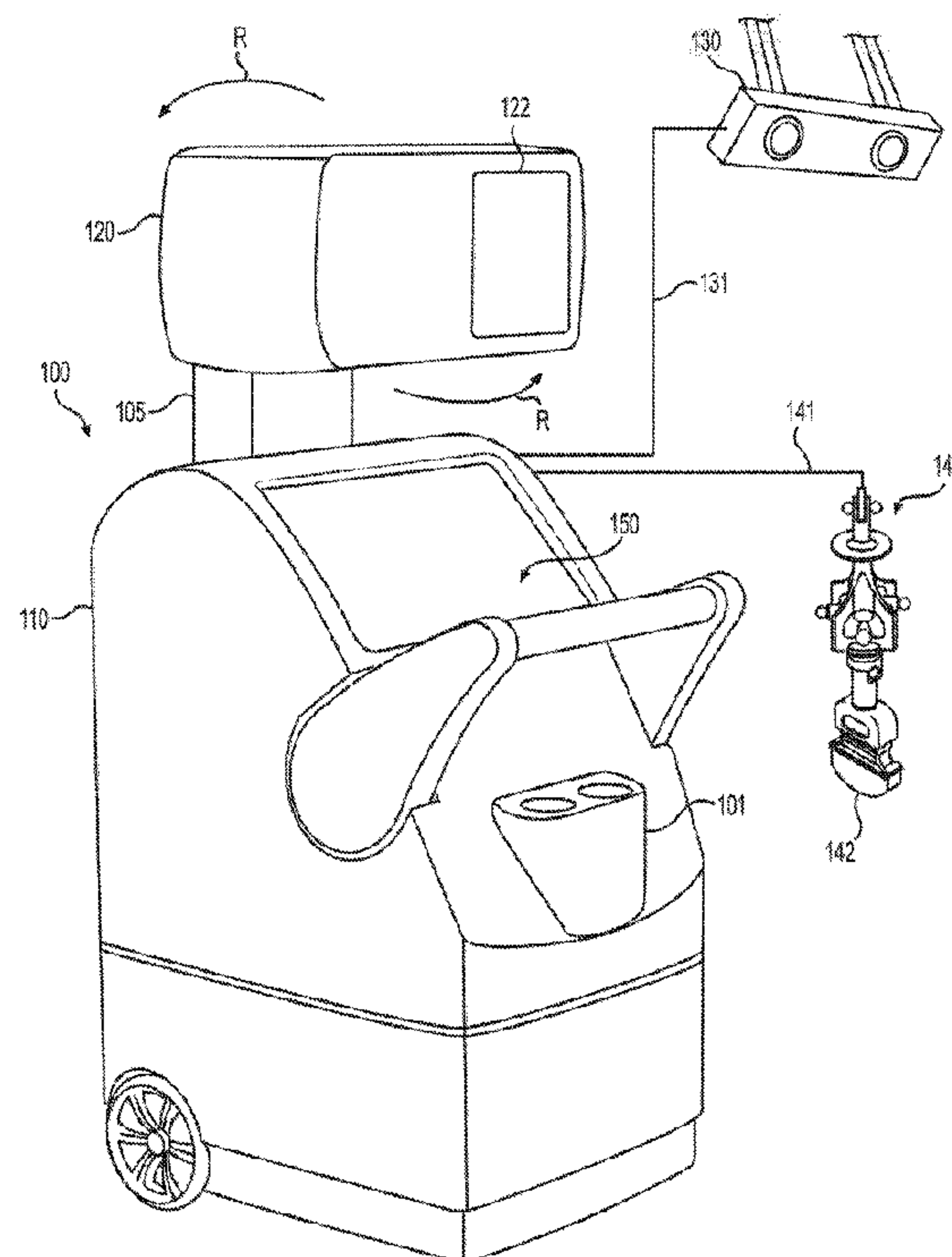


FIG. 1A

(57) **Abrégé/Abstract:**

The tissue imaging system incorporates an integrated X-Ray -and Ultrasound Imaging system, The X-Ray system is used for imaging and generating a 3D Volume of the extracted tissue sample (specimen). The Ultrasound Imaging system is used for imaging the body area of interest of the patient from which the tissue sample is to be extracted. On the display of the system, the physician, draws contours on the area of interest and the same is displayed as a 3D Volume. A 3D volume of the extracted tissue is generated using the x-ray imaging sub-system. Quantitative analysis is performed on the two 3D volumes (extracted tumor x-ray imaging and the contoured ultrasound imaging) to determine the difference between the contoured and the surgically extracted specimen to assist the physician in determining if further, surgical intervention is required.

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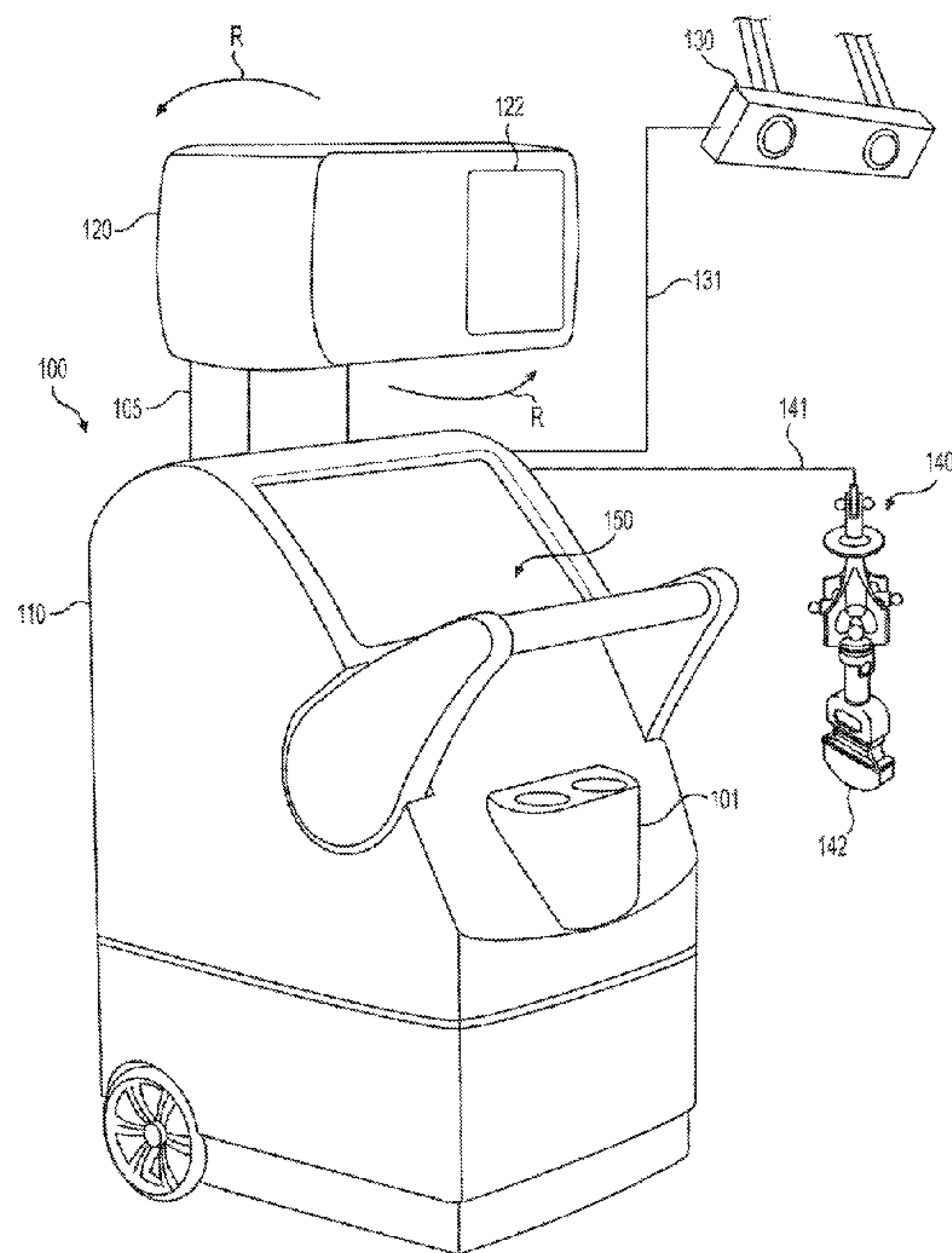
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(54) Title: TISSUE IMAGING SYSTEM AND METHOD FOR TISSUE IMAGING

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**FIG. 1A**

TISSUE IMAGING SYSTEM AND METHOD FOR TISSUE IMAGING

CROSS REFERENCE TO RELATED APPLICATION

5 **[0001]** This application claims priority under 35 U.S.C. §119 to U.S. Provisional Patent Application No. 62/490,021, filed on April 25, 2017, hereby incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

10 **[0002]** The invention generally relates to the field of medical devices, and more particularly to tissue imaging devices, systems and methods utilizing both ultrasound imaging and X-ray imaging in the removal of cancerous, necrotic or other diseased tissue from a body, such as from a human body, animal body or reptilian body, and generating three dimensional (3D) ultrasound images and 3D X-ray images of tissue prior to and after its removal from the
15 body to determine whether the desired amount or volume of the cancerous, necrotic or other diseased tissue has been removed from the body.

BACKGROUND

[0003] Imaging devices, such as using ultrasound imaging or X-ray imaging, are commonly used in diagnosis for treatment of various medical issues, such as injury to bones and
20 detecting cancerous tissue in a body. One such use, for example, is the use of imaging type diagnostic tools in the detection of breast or prostate cancer, for example. Clearly, early detection of cancerous tissue and accurately removing such diseased tissue from a body can increase the likelihood of preventing the cancer from spreading or metastasizing throughout the

body, as well as can minimize the need for additional surgical procedures involving excision of cancerous, necrotic or other diseased tissue.

[0004] The excising of cancerous, necrotic or other diseased tissue can, in some instances, be relatively complex, particularly to assure that the appropriate amount or volume of cancerous, necrotic or other diseased tissue, as typically also includes an amount of adjacent healthy tissue, is removed as an added precaution to minimize the re-occurrence or spreading in the body of the cancerous, necrotic or other diseased tissue. Pre-surgical diagnostics can employ X-ray imaging, for example, to determine the size, volume, and the location in the body of the cancerous, necrotic or other diseased tissue. The location of the tissue to be removed is appropriately marked, such as by a suitable marker or guidewire. Once the cancerous, necrotic or other diseased tissue is removed from the body, X-ray imaging, for example, typically can be employed to determine if the outer areas of the removed tissue do not include the cancer, or necrosis or other diseased tissue. Whereupon if it is determined from analysis of the diagnostic imaging of the removed tissue additional tissue needs to be removed, the above described procedure of tissue removal and diagnostic examination of the removed tissue is repeated, as necessary, until it is determined that the amount and volume of removed tissue is a correct amount.

[0005] X-ray imaging of removed tissue typically provides two dimensional (2D) images, with the removed tissue being rotated to obtain differing images thereof for the tissue analysis. However, traditional two dimensional (2D) X-ray imaging may be disadvantageous as typically involving a relatively long time period for analysis, as well as can likely increase the likelihood of inaccurate measurements, such as from movement of the tissue sample during X-ray imaging, and considering that it is typically performed under time constraints in relation to

being performed during the time the person or animal is undergoing the surgical removal procedure. Another tissue analysis technique employed can involve digital tomosynthesis which utilizes digital image capture and processing with a detector motion providing images similar to conventional tomography, but typically the images can have a limited field depth, but can possibly save time for sample analysis in that image slices at various depths and thickness can be provided.

[0006] Considering the advantages and limitations of X-ray and digital tomosynthesis systems, a cabinet specimen tomosynthesis system has been proposed for specimen imaging in U.S. Patent No. 9,138,193 to Lowe et al. issued on September 22, 2015, entitled "Specimen Radiography With Tomosynthesis In A Cabinet" (the "'193 Patent"), incorporated by reference herein in its entirety. In the '193 Patent, X-ray imaging and digital tomosynthesis are utilized in a method and system for producing tomosynthesis images of a breast specimen in a cabinet x-ray system is disclosed.

[0007] In the '193 Patent system, it is disclosed that an X-ray source delivers X-rays through a specimen of excised tissue and forms an image at a digital X-ray detector. Multiple X-ray images are taken as the X-ray source moves relative to the stationary breast specimen. It is disclosed that, desirably, the X-ray source moves in a range from about 350 degrees to and including about 10 degrees. The X-ray source can travel substantially along a path that generally defines an arc, or linearly, while the digital X-ray detector remains stationary throughout and the source remains substantially equidistant from the specimen platform. The '193 Patent further discloses that the set of X-ray image data taken at the different points are combined to form a tomosynthesis image that can be viewed in different formats, alone or as an adjunct to conventional specimen radiography. The '193 Patent further discloses reconstructing three-

dimensional tomosynthetic x-ray images from two-dimensional projection x-ray images in real-time and on-demand.

[0008] While the cabinet specimen tomosynthesis system disclosed in the '193 patent appears to offer advantages in specimen analysis, the disclosed '193 patent specimen analysis appears to rely primarily on human judgment in reading the images of the removed tissue to determine whether an appropriate amount of diseased tissue and adjacent non-diseased marginal tissue has been removed. Since the '193 Patent system appears to rely on human judgment in the determination of the sufficiency of tissue removed, and which judgment appears to be based only on the reconstructed images of the excised tissue, the likelihood of error can potentially still be affected by one or more of the human reviewer and/or the quality or accuracy of the reconstructed image of the excised tissue. Further, it appears the '193 patent system image analysis does not provide a system and method for an image comparison of the excised tissue with that of the tissue to be removed as present in the body.

[0009] Further, ultrasound imaging has been employed in various medical applications to provide ultrasound images of various body portions and bodily tissue as, for example, in U.S. Patent No. 6,961,405 to Scherch issued on November 1, 2005 entitled "Method And Apparatus For Target Position Verification" (the "405 Patent"), incorporated by reference herein in its entirety.

[0010] In the '405 patent, a system and method is disclosed for aligning the position of a target within a body of a patient to a predetermined position used in the development of a radiation treatment plan. The apparatus includes an ultrasound probe used for generating live ultrasound images, a position sensing system for indicating the position of the ultrasound probe with respect to the radiation therapy device, and a computer system. The '405 patent apparatus

discloses an ultrasound probe that generates two-dimensional ultrasound images of the portion of a patient's body containing the target, while patient is on a treatment table. The computer system is used to display the live ultrasound images of a target in association with representations of the radiation treatment plan, to align the displayed representations of the radiation treatment plan with the displayed live ultrasound images, to capture and store at least two two-dimensional ultrasound images of the target overlaid with the aligned representations of the treatment plan data, and to determine the difference between the location of the target in the ultrasound images and the location of the target in the representations of the radiation treatment plan.

[0011] Thus, the '405 patent system advantageously provides two-dimensional ultrasound images of the portion of a patient's body to align the displayed representations of the radiation treatment plan with the displayed live ultrasound images, so as to determine the difference between the location of the target in the ultrasound images and the location of the target in the representations of the radiation treatment plan. However, it appears the '405 patent system and method likewise does not specifically disclose a tissue imaging system and method for an image comparison of excised tissue from a body with that of the tissue to be removed as present in the body.

[0012] Also, various systems have been employed to track the position and orientation of an object in medical applications. In this regard, knowledge of the position of a surgical tool during neurosurgery or location of a target such as a tumor while radiation therapy treatment is occurring, have always been important considerations. The position of an object or tool is typically defined by three translation parameters (x, y, z) and three rotation parameters (pitch, roll, yaw) corresponding to six degrees of freedom. The translation parameters (x, y, z) indicate three-dimensional position, e.g. forward and back (y-axis), left and right (x-axis), up and down

(z-axis), and three rotation parameters (pitch, roll, yaw) indicate orientation of the tool or object, e.g. rotation about the x-axis (pitch), rotation about the y-axis (roll), and rotation about to the z-axis (yaw).

[0013] Various systems are known for determining the spatial position and orientation of an object. One such system includes use of a mechanical arm to track the location of a medical tool or probe which can be used to further determine the location of a target. In order to locate the target, the tool or probe can be affixed to the mechanical arm having a known reference position. A computer system tracks the tool or probe while an operator repositions the tool or probe along with the mechanical arm. The geometry of the mechanical arm is known such that movement of the tool or probe in conjunction with the mechanical arm provides the computer system continuous position information regarding the tool or probe. In an invasive procedure, the tool or probe can have a fixed length. Thus, contacting the target with the end of the tool can provide a position location of the target. Ultrasound has also been employed to track the position and orientation of an object in medical applications. In a noninvasive procedure, a probe, such as an ultrasound device, can be used to locate both the position and the orientation of the target.

[0014] Also, both active and passive emission techniques are known which operate by projecting a geometric representation or extension of the object or tool formed by the emitters onto the field of view of a pair of spaced sensors. Various implementations of sensors have been used, one being the use of two cameras positioned spaced apart a known distance and angled in the general direction of the object or tool such that the three-dimensional position of the object or tool can be obtained by triangulation from the positions of the emitters. For example, a camera

or opti-electrical motion measurement system, known as the Polaris®, by Northern Digital Inc., Ontario Canada, has been used for triangulating the position of optically trackable tools.

[0015] Specifically, a computer system, using mathematical processing, can determine the three dimensional coordinates of each one of the emitters associated with the object or tool.

5 The position of each of the emitters can be used to determine the position of the object or tool relative to a three dimensional coordinate system centered at a preselected point in space, typically at a point fixed relative to the sensors. The positional relationship to each other of each of the emitters associated with the object or tool can be utilized to further determine the orientation in space of the object or tool. Generally, at least three of the emitters must be
10 detected and must be unobscured by any adjacent emitters. Additionally, the sensors generally require the emitters to be a minimum distance, for example, 3-5 cm apart. In theory, such systems can provide three unobstructed emitters for most of a sphere created by the six degrees of freedom. One of the more modern types of passive emission system utilizes passive retro-reflectors which can be affixed to the object or tool and which reflect directly back to a pair of
15 active emitter arrays adjacent a pair of optical sensors. This type of system allows the optical sensors to be positioned relatively close together.

[0016] For example, a system to track the position and orientation of an object, such as for medical applications in medical applications is described in in U.S. Patent No. 7,289,227 to Smetak et al. issued on October 30, 2007 entitled "System And Tracker For Tracking An Object,
20 and Related Methods" (the "'227 Patent"), incorporated by reference herein in its entirety.

[0017] In the '227 patent, there is disclosed a system to track a three-dimensional position and an orientation of a movable object and associated methods are provided. The system includes a tracker having an optically trackable body adapted to connect to the movable

object. A plurality of optical indicators are connected or mounted to the optically trackable body to form a plurality of geometric figures. A plurality of obfuscating flanges optically separate the optical indicators from each other to prevent each of the optical indicators from becoming optically coincident with another optical indicator when viewed along a preselected viewing path. The system also includes an apparatus to track the tracker having an optical detector to simultaneously detect the three-dimensional position of at least three of the plurality of optical indicators and a determiner to determine the three-dimensional position and orientation of the optically trackable body from the position of the optical indicators.

[0018] However, it appears the '227 patent system and method, as well as the above referred to systems that have been employed to track the position and orientation of an object, such as in medical applications, likewise do not specifically disclose a tissue imaging system and method for an image comparison of excised tissue from a body with that of the tissue to be removed as present in the body.

[0019] It is believed that there is a need for a tissue imaging device, system and method that can enhance the accuracy and efficiency, as well as can assist in reducing the possibility of human error, in determining whether and appropriate amount of cancerous, necrotic or other diseased tissue has been removed from a body, such as of a person, animal or reptile. Also, in view of the foregoing, there is believed to be a need to provide a compact and versatile tissue imaging system as can readily provide assistance, such as to a human or veterinary surgeon or doctor, in real time, such as during a surgical procedure for the tissue removal to enhance the confidence level that a correct amount of the cancerous, necrotic or other diseased tissue has been removed from a body.

[0020] Further there is believed to be a need, as well as it would be advantageous to have, an integrated cabinet type tissue imaging system for specimen imaging that provides generated 3D images of the removed and to be removed tissue and compare the generated 3D images of the removed and to be removed tissue to facilitate accurately indicating, such as to a surgeon in an operating room, that that the cancerous, necrotic or other diseased tissue, as well as an appropriate margin of healthy tissue around the cancerous, necrotic or other diseased tissue has been excised in an expedient manner and to enhance the probability of successful removal, while reducing the likelihood of human error.

[0021] Further, a tissue imaging device, system and method is believed to be needed that utilizes and combines the benefits of ultrasound imaging of bodily tissue and the benefits of X-ray imaging of specimens in the removal of cancerous, necrotic or other diseased tissue from a body, such as from a human body, animal body or reptilian body, so as to provide generated three dimensional (3D) ultrasound images of the tissue to be removed present in the body for comparison with generated 3D X-ray images of the removed tissue to increase the accuracy of the representations of the imaged tissue to facilitate the accuracy and ease of comparison in the determination of whether the desired amount or volume of the cancerous, necrotic or other diseased tissue has been removed from the body.

[0022] Thus, a compact, efficient, accurate and integrated tissue imaging device, system and method utilizing both ultrasound imaging and X-ray imaging in the removal of cancerous, necrotic other diseased tissue from a body to facilitate determining whether an appropriate or correct amount or volume of cancerous, necrotic other diseased tissue has been removed from the body addressing the aforementioned problems or shortcomings is desired.

SUMMARY OF INVENTION

[0023] An embodiment of a tissue imaging system includes an x-ray imaging subsystem and an ultrasound imaging subsystem. The x-ray imaging subsystem includes an x-ray tube, a digital flat panel, a specimen tray, x-ray beam generator & controller, x-ray angle controller, and x-ray analysis processor and memory to store x-ray images. The ultrasound imaging subsystem includes an ultrasound probe assembly (ultrasound probe attached to a holder with 3D infrared markers), a 3D infrared imaging camera, probe 3D position and orientation detector, ultrasound beamformer, and the ultrasound analysis processor and memory to store ultrasound images. The system also includes a computer having an image fusion processor and memory to perform ultrasound and x-ray 3D volume fusion and store results of fusion analysis. The computer also has a user interface device (monitor) to display results and control the system.

[0024] The method includes having the patient lie on the operating room (treatment) table, providing an ultrasound probe to perform ultrasound imaging of the area of interest and displaying the live ultrasound image. More specifically, as the ultrasound probe is moved and rotated, tracking the 3D position and orientation of the ultrasound probe and displaying the information on the user interface.

[0025] The method also includes the drawing of contours on the ultrasound images to mark the tissue structure to be extracted. These contours are drawn on the ultrasound images acquired at different probe orientations and positions. Advantageously, the ultrasound analysis processor in the computer generates a 3D volume of the ultrasound and the contoured tissue structure and provides measurement information that includes the height, width, length, and volume of the contoured tissue.

[0026] The method also includes extracting the tissue structure/specimen and placing it onto the specimen tray of the x-ray subsystem and performing x-ray imaging. More specifically,

performing the x-ray imaging includes rotating the x-ray tube and the flat-panel detector around the stationary specimen in the specimen tray and acquiring multiple x-ray images and generating a 3D volume of the specimen from x-ray images. The x-ray analysis processor in the computer system provides measurement information that includes the height, width, length, and volume of the extracted specimen.

[0027] The method also includes fusion of the 3D volumes of the tissue contoured on the ultrasound image and the extracted tissue imaged via the x-ray subsystem by the fusion processor in the computer system. More specifically, overlaying one volume over the other for visual representation of the difference and performing quantitative analysis by determining/calculating the difference in volume, length, width and height of the two volumes. The visualization of 3D volumes overlaid on top of each other and the determined differences has the advantage of providing quantitative feedback on the error in specimen extraction facilitates preventing subjectivity in deciding on the amount of tissue to be extracted.

[0028] The method also includes performing biopsies under ultrasound guidance. The method enables marking of biopsy needles visualized in a 2D live ultrasound image and visualizing in a 3D ultrasound volume to provide an accurate representation of the angle and the position of the biopsy needle with respect to the structure being biopsied. In addition, the method provides the capability of visualizing all the biopsies performed on the tissue by displaying the needle paths of all biopsies in 2D and 3D ultrasound visualized on the user interface.

[0029] These and other features of the present invention will become readily apparent upon further review of the following specification and drawings.

DESCRIPTION OF THE DRAWINGS

[0030] Figure 1A is a perspective view of an embodiment of a tissue imaging system, according to the present invention.

[0031] Figure 1B is a schematic perspective view of an embodiment of the tissue imaging system of FIG. 1A, according to the present invention.

[0032] Figure. 2A is an environmental perspective view showing the tissue imaging system of Figures 1A and 1B obtaining ultrasound images of a portion of a body, according to the present invention.

[0033] Figure. 2B is an environmental perspective view showing an embodiment of the tissue imaging system of Figures 1A and 1B obtaining ultrasound images of another portion of a body, according to the present invention.

[0034] Figure. 2C is an environmental perspective view showing an embodiment of the tissue imaging system of Figures 1A and 1B obtaining ultrasound images of a portion of a body in the area of the prostate, according to the present invention.

[0035] Figure. 2D is an environmental perspective view showing an embodiment of the tissue imaging system of Figures 1A and 1B illustrating obtaining ultrasound images in various portions of a body, according to the present invention.

[0036] Figure 3 is a schematic illustration of components of an embodiment of a controller, an ultrasound sub-system, and X-ray sub system, and an ultrasound and X-Ray image fusion sub-system of an embodiment of the tissue imaging system of Figures 1A and 1B, according to the present invention.

[0037] Figure 4 is a schematic perspective view of an embodiment the tissue imaging system of Figures 1A and 1B illustrating tracking position and orientation of an ultrasound probe

of the system in obtaining and transmitting ultrasound images of a portion of a body, according to the present invention.

[0038] Figure 5 is an exploded perspective view of an embodiment of an ultrasound probe in an embodiment of a tissue imaging system of Figures 1A and 1B, according to the present invention.

[0039] Figure 6 is an exploded perspective view of an embodiment of an optically trackable body of an ultrasound probe with tracker system for tracking position and orientation in an embodiment of the tissue imaging system of Figures 1A and 1B, according to the present invention.

[0040] Figure 7 is perspective view of an embodiment of an optically trackable body of an ultrasound probe with tracker system for tracking position and orientation in an embodiment of the tissue imaging system of Figures 1A and 1B, according to the present invention.

[0041] Figure 8 is a perspective view of an embodiment of an optically trackable body illustrating tracking position and orientation using the optically trackable body in an embodiment of the tissue imaging system of Figures 1A and 1B, according to the present invention.

[0042] Figure 9 is a schematic illustration of an embodiment of an X-ray chamber in an embodiment of the tissue imaging system of FIG. 1A, according to the present invention.

[0043] Figure 10 is a perspective view of an embodiment of the tissue imaging system of Figures 1A and 1B in conjunction with a schematic illustration of an embodiment of an X-ray chamber of the tissue imaging system, according to the present invention.

[0044] Figure 11 is a schematic illustration of an embodiment of an interface display illustrating a sub-display of a generated 2D ultrasound image of a contoured tissue portion for removal from a body and a sub-display of a generated 3D X-ray image of the contoured tissue

portion for removal from the body in an embodiment of the tissue imaging system of Figures 1A and 1B, according to the present invention.

[0045] Figure 12A is a schematic illustration of an embodiment of an interface display illustrating a sub-display of the generated 3D ultrasound image of the contoured tissue portion for removal from the body of Figure 11 and a sub-display of a generated 3D X-ray image of a tissue specimen removed from the body in an embodiment of the tissue imaging system of Figures 1A and 1B, according to the present invention.

[0046] Figure 12B is a schematic illustration of an embodiment of an interface display illustrating a sub-display of the generated 3D ultrasound image of the contoured tissue portion for removal from the body superimposed upon the generated 3D X-ray image of the tissue specimen removed from a body illustrating a difference volume between the contoured tissue portion for removal from the body and the tissue specimen removed from the body in an embodiment of the tissue imaging system of Figures 1A and 1B, according to the present invention.

[0047] Figure 13 is a perspective view of an embodiment of the tissue imaging system of Figures 1A and 1B in conjunction with a schematic illustration of an embodiment of an X-ray chamber of the tissue imaging system for tissue biopsy sample imaging, according to the present invention.

[0048] Figure 14 is a schematic illustration of an embodiment of an X-ray chamber for tissue biopsy imaging in an embodiment of the tissue imaging system of Figures 1A and 1B, according to the present invention.

[0049] Figure 15A is a schematic illustration of an embodiment of an interface display illustrating a sub-display of the generated 3D ultrasound image of a contoured tissue portion for

removal from the body superimposed upon a generated 3D X-ray image of the tissue specimen removed from a body illustrating where the difference volume indicates there is no substantial difference in volume between the contoured tissue portion for removal from the body and the tissue specimen removed from the body in an embodiment of the tissue imaging system of
5 Figures 1A and 1B, according to the present invention.

[0050] Figure 15B is a schematic illustration of an embodiment of an interface display illustrating a sub-display of the generated 3D ultrasound image of a contoured tissue portion for removal from the body superimposed upon a generated 3D X-ray image of the tissue specimen removed from a body illustrating where the difference volume indicates there is a difference in
10 volume between the contoured tissue portion for removal from the body and the tissue specimen removed from the body in an embodiment of the tissue imaging system of Figures 1A and 1B, according to the present invention.

[0051] Figure 16A is an exemplary flow chart for an embodiment of a process for determining a difference volume between a contoured tissue portion for removal from the body and a tissue specimen removed from the body using 3D generated X-ray and 3D generated
15 ultrasound images in conjunction with an embodiment of the tissue imaging system of Figures 1A and 1B, according to the present invention.

[0052] Figure 16B is an exemplary flow chart for an embodiment of a process for generating X-ray imaging of a biopsy tissue sample in conjunction with an embodiment of the
20 tissue imaging system of Figures 1A and 1B, according to the present invention.

[0053] Figure 17 is perspective view of an embodiment of the tissue imaging system of Figures 1A and 1B illustrating using ultrasound imaging for placement of one or more

radioactive markers in tissue in a portion of a body for localization, according to the present invention.

[0054] Figure 18A is a schematic illustration of an embodiment of an interface display illustrating a sub-display of the generated 2D ultrasound image of a tissue portion in a body and
5 a generated 3D ultrasound image of the tissue portion of the body for biopsy needle guidance and placement in an embodiment of the tissue imaging system of Figures 1A and 1B, according to the present invention.

[0055] Figure 18B is a schematic illustration of an embodiment of an interface display illustrating a sub-display of the generated 2D live ultrasound image of a tissue portion in a body
10 and a sub-display of a generated 3D ultrasound image of the tissue portion of the body corresponding to the generated 2D live ultrasound image for biopsy needle guidance and placement and for marking and reviewing the biopsy in an embodiment of the tissue imaging system of Figures 1A and 1B, according to the present invention.

[0056] Figure 18C is a schematic illustration of an embodiment of an interface display
15 illustrating a sub-display of a generated 2D ultrasound image of a plurality of biopsy samples taken of a tissue portion in a body and a sub-display of a generated 3D ultrasound image of the tissue portion of the body corresponding to the generated 2D ultrasound image for a plurality of biopsy paths corresponding to biopsy samples taken of a tissue portion in a body for reviewing a biopsy procedure in an embodiment of the tissue imaging system of Figures 1A and 1B,
20 according to the present invention.

[0057] Figure 19 is an exemplary flow chart for an embodiment of a process for generating 2D and 3D X-ray imaging of a biopsy tissue sample in conjunction with biopsy needle guidance and biopsy procedure review and for visualizing imaging for placement of one

or more radioactive markers in tissue in a portion of a body for localization in conjunction with an embodiment of the tissue imaging system of Figures 1A and 1B, according to the present invention.

[0058] Unless otherwise indicated, similar reference characters denote corresponding features consistently throughout the attached drawings.

DETAILED DESCRIPTION

[0059] Referring now to Figure 1A, there is illustrated a tissue imaging system **100**. The system **100** includes a main body **110**, an X-Ray Chamber **120**, a neck **105**, an interface display **150**, and an Infrared 3D Imaging Camera **130**. The neck **105** connects the X-Ray Chamber **120** with the main body **110**. The neck **105** also provides a support/anchor for the X-Ray Chamber **120** to rotate in the arrowed direction **R** about its central axis. The ultrasound probe with tracker system **140** includes or incorporates an ultrasound probe **142**. Also, the imaging system **100** can include a holder **101** that can house an ultrasound probe and an ultrasound gel or other items for the imaging procedure, for example.

[0060] Referring to Fig., 1B, there is schematically illustrated the main body **110** that includes an X-Ray Generator, to be described, within the X-Ray Chamber **120**, an X-ray controller system **160** for controlling various operations of the X-ray imaging generation and processing in the imaging system **100**, an ultrasound beamformer system **170** for generating and processing ultrasound images and communicates via a wired or wireless communication **141** with the ultrasound probe with tracker system **140** and via a wired or wireless communication **131** with the Infrared 3D Imaging Camera **130** in the imaging system **100**. Also, the main body **110** includes an Image Comparison and Generation System **180** that communicates with the X-ray controller system **160** and with the ultrasound beamformer system **170** for control, imaging,

visualization, measurement, comparison and analysis in the generation of the 2D and 3D ultrasound and X-ray images in the system 100, as schematically indicated in Figure 1B.

[0061] Referring to Figure 2A, the ultrasound probe with tracker system 140 can be connected via a wired or wireless connection to the main body 110. Similarly, the Infrared 3D Imaging Camera 130 can be connected to the main body 110 via a wired or wireless connection. Figure 2A also shows the patient P lying supine on the Operating Table T with the ultrasound probe 142 imaging the breast at location L1.

[0062] As shown in Figure 2B and 2C, the ultrasound probe 142 is being used for imaging different parts of the patient P body at locations L2, L3, for example. In addition, Figure 2D indicates that the system 100 with the ultrasound probe with tracker system 140 can be used for imaging a plurality of different parts of the body at locations or areas A1, A2, A3, A4, for example.

[0063] Figure 3 is the schematic representation of the hardware, firmware and/or software system components 300 of the tissue imaging system 100. The components 300 are integrated with the Image Comparison and Generation System 180, the X-ray controller system 160 and the ultrasound beamformer system 170 for control, imaging, visualization, measurement, comparison and analysis in the generation of the 2D and 3D ultrasound and X-ray images in the system 100 in performing various operations and processes in the image generation in the imaging system 100.

[0064] Referring to the system components 300 of Fig 3, a main control system 310 includes the controller processor 312 and a main memory 314 that controls the ultrasound subsystem 340, an X-Ray subsystem 320, an Image Fusion generator 360, and a user interface 152. The ultrasound subsystem 340 includes the hardware, firmware and/or software

components for ultrasound based tissue imaging. An ultrasound probe 3D position and orientation detector **341** connects to the Infrared 3D Imaging Camera **130** to determine the position and orientation of the 3D markers on the ultrasound probe with tracker system **140**. An Ultrasound beamformer **342** controls and reads the data from the ultrasound probe **142** to
5 generate 2D ultrasound images via the ultrasound 2D image generator **345a**. The ultrasound beamformer **342** can be a suitable commercially available beamformer, such as, for example, an HBU Beamformer Board, Sonoscaner, Paris, France. An ultrasound processor memory **343** stores the 2D images, and the position and orientation information that is used by an ultrasound analysis processor **345**. An ultrasound 3D volume generator **345c** uses the 2D ultrasound images
10 and an ultrasound probe position and orientation (angle) calculator **345b** to generate 3D volume of the ultrasound images and the 3D tumor volume. An ultrasound measurement and analysis program **345d** provides tools to contour the 2D ultrasound images to mark the tumor, and perform measurements. The x-ray subsystem **320** contains the hardware, firmware and/or software components required for tissue specimen (for example lumpectomy) and biopsy
15 specimen imaging. The x-ray tube **321** generates the x-rays as per the settings specified by an x-ray beam generator and controller **324**. The digital flat panel detector system **323** receives the x-rays that pass through the specimen **SP** placed in a specimen tray **322**, **328**, generates the x-ray image, and stores it in an x-ray processor memory **326** to be used by an x-ray analysis processor
20 **327** for further processing and analysis. An x-ray angle controller **325** controls the rotational angle in of the x-ray chamber **120** to allow for 360° rotation for imaging the tissue specimen **SP** from different angles. X-ray imaging of the specimen **SP** from each angle is used by an x-ray 2D image generator **327a** to generate a 2D image of the specimen **SP**. The plurality of these 2D x-ray images generated from different angles are used by an x-ray 3D image generator **327b** to

generate 3D volume of the specimen **SP**. An x-ray measurement/analysis program **327c** uses the 2D and 3D volume data of the x-ray to provide length [X] **1151**, width [Z] **1153**, height [Y] **1152** and volume **1154** information of the specimen **SP** imaged by the x-ray system (see, Figure 11). An image fusion generator **360** contains a fusion processor memory **361** and a fusion processor **362** that stores and processes the 3D volumes of the ultrasound and x-ray. An ultrasound + x-ray 3D fusion **363** module creates the fusion of the 3D volumes of ultrasound and x-ray images and a fusion measurement analyzer **364** calculates or determines the difference in the two volumes. The user interface **152** in conjunction with the interface display **150** provides controls to the user to control the imaging system **100** and displays the required information as described in Figures 11, 12A, 12B, 15A, 15B, 18A, 18B and 18C.

[0065] Fig. 3 illustrates a generalized system **100** and the above described system components **300** for control, imaging, visualization, measurement, comparison and analysis in the generation of the 2D and 3D ultrasound and X-ray images in the system **100**, although it should be understood that the imaging system **100** and system components **300** can represent, for example, a stand-alone computer, computer terminal, portable computing device, networked computer or computer terminal, or networked portable device. Data may be entered into the system **100** by the user via any suitable type of user interface **152**, and can be stored in computer readable memories of the system components **300**, such as memories **314**, **343**, **326** and **361**, which may be any suitable type of computer readable and programmable memory. Calculations, processing and analysis are performed by the controller/processor **312** or other processors of system components **300** of the system **100**, which can be any suitable type of computer processor, and can be displayed to the user on the interface display **150**, which can be any suitable type of computer display, for example.

[0066] The controller/processor **312** and other processors of the system components **300** can be associated with, or incorporated into, any suitable type of computing device, for example, a personal computer or a programmable logic controller (PLC) or an application specific integrated circuit (ASIC). The interface display **152**, the processor components of the system components **300** and the memories of the system components **300**, and any associated computer readable media are in communication with one another by any suitable type of data bus or other wired or wireless communication, as is well known in the art.

[0067] Examples of computer readable media include a magnetic recording apparatus, non-transitory computer readable storage memory, an optical disk, a magneto-optical disk, and/or a semiconductor memory (for example, RAM, ROM, etc.). Examples of magnetic recording apparatus that may be used in addition to memories of the system components **300**, or in place of memories of the system components **300**, include a hard disk device (HDD), a flexible disk (FD), and a magnetic tape (MT). Examples of the optical disk include a DVD (Digital Versatile Disc), a DVD-RAM, a CD-ROM (Compact Disc-Read Only Memory), and a CD-R (Recordable)/RW.

[0068] Referring now to Figure 4, there is illustrated a schematic perspective view of an embodiment the tissue imaging system **100** Figures 1A and 1B illustrating tracking position and orientation of the ultrasound probe with tracker system **140** of the imaging system **100** in obtaining and transmitting ultrasound images of a portion of a body according to the present invention.

[0069] As illustrated in Figure 4, embodiments of the present invention advantageously provide the imaging system **100**, the infrared 3D Imaging Camera **130**, and ultrasound probe with tracker system **140** having the ultrasound probe **142** for tracking a three-dimensional

position and an orientation of the tracker system 140, the ultrasound probe 142 obtaining 2D ultrasound images of the tissue or organs in an area of the body of interest. The infrared 3D Imaging Camera 130 can simultaneously detect the three-dimensional position of at least three of the plurality of optical retro-reflective spheres 525 (Fig. 5) indicated by the positional information being detected by the wireless communication "D", and the ultrasound probe 3D position and orientation detector 341 receiving position information from the imaging camera 130 to determine the three-dimensional position and orientation of the optically trackable body 523 (Fig. 6) from the detected three-dimensional position of the optical retro-reflective spheres 525, and thus, the three-dimensional position and orientation of the tracker system 140. The optically trackable body 523 can be connected to ultrasound probe 142 by various suitable connectors known to those skilled in the art to include various movable object mounts, such as movable object mount 675, 667.

[0070] Also, the ultrasound probe 142 can include an ultrasonic sensor adapted to locate a three-dimensional position of an area of interest of a body, such as tumor tissue, with respect to a position of the ultrasound probe 142. Desirably, the ultrasound probe 142 includes an ultrasound image generator, such as typically available in a commercially available ultrasound probe such as, for example, PR14 Linear Probe 10-17 MHZ, Sonoscanner, Paris, France. The ultrasound probe 142 can generate two-dimensional ultrasound images of the portion of the patient P containing the area of interest within the body. Such as a person or animal, is on the treatment table T.

[0071] The infrared 3D Imaging Camera 130 typically includes a body 132 having a wired or wireless communication with ultrasound sub system 340 in the main body 110 of the imaging system 100. The infrared 3D Imaging Camera 130 has an optical detector body 132

positioned separate and spaced apart from the optically trackable body 523 at a predetermined three-dimensional sensor reference location. The infrared 3D Imaging Camera 130 desirably includes a pair of separate and spaced apart optical receivers 133, 135, connected to the optical detector body 132, each having a field of view and being adapted to receive optical energy
5 emitted or reflected by each of the plurality of optical retro-reflective spheres 525 when positioned in the field of view typically (centered about the optical receiver pointing angle). The optical receivers 133, 135 detect the three-dimensional sphere position of each of the plurality of retro-reflective spheres 525 when positioned simultaneously within the field of view of both of the optical receivers 133, 135 to produce a plurality of position signals representing the position
10 of such three-dimensional retro-reflective spheres 525. Each of the optical receivers 133, 135, can include a photo-sensitive array (not shown) such as a two-dimensional array charge coupled device CCD sensor or other similar device, defining a photosensor, to detect optical energy radiated from the retro-reflective spheres 525 when positioned in the field of view of the optical receiver 133, 135. The photosensor provides electrical signals representative of positional
15 information of the retro-reflective spheres 525. Each of the optical receivers 133, 135, also generally includes a lens for focusing the optical energy from the retro-reflective spheres 525 on the photosensor. Also, the infrared 3D Imaging Camera 130 can be any of various suitable cameras, as are well-known to those skilled in the art as, for example, a camera or opti-electrical motion measurement system, known as the Polaris.®, by Northern Digital Inc., Ontario Canada.

20 **[0072]** Where the plurality of indicators are in the form of the optical retro-reflective spheres 525, the Infrared 3D Imaging Camera 130 can include a pair of infrared illuminators, desirably in the form of a pair of directional infrared illuminator (arrays) 137, 139. The first illuminator 137 is positioned in a surrounding relationship adjacent optical receiver 133 and the

second illuminator 139 is positioned adjacent the other optical receiver 135 to selectively illuminate each of the plurality of optical retro-reflective spheres 525 when positioned in the field of view of the respective adjacent optical receiver 133, 135. This provides the requisite optical energy necessary to view the optical retro-reflective spheres 525 within the field of view of the respective adjacent optical receiver 133, 135.

[0073] The ultrasound probe 3D position and orientation detector 341 of the ultrasound subsystem 340 is in communication with the infrared 3D Imaging Camera 130 and is responsive to the plurality of position signals produced by the infrared 3D Imaging Camera 130 to determine the three-dimensional retro-reflective sphere 525 position of each of the plurality of retro-reflective spheres 525 when positioned simultaneously within the field of view of both of the optical receivers (133, 135) of the infrared 3D Imaging Camera 130. The ultrasound subsystem 340 including ultrasound probe 3D position and orientation detector 341 in conjunction with the controller processor 312 analyzes the two-dimensional position of each sphere 525 in the field of view of both receivers 133, 135, with respect to the position on the photosensor, to determine the three-dimensional location of each sphere 525 simultaneously in the field of view of the receivers 133, 135. The main memory 314 accessible by the controller processor 312 to store a table of definitions containing the segment lengths "S" (Fig.8) between each pair of the plurality of optical retro-reflective spheres 525.

[0074] The Infrared 3D Imaging Camera 130 can be used to view the reflective spheres 525 positioned in its field of view, and thus, view at least one of the plurality of geometric figures F (Fig. 8). The ultrasound sub-system 340 including ultrasound probe 3D position and orientation detector 341 can then be used to identify which one of the plurality of geometric figures F is positioned in the field of view of the Infrared 3D Imaging Camera 130. A lookup

table containing various segment lengths between pair combinations of the retro-reflective spheres 525, or similar collection of data, can be used, as can be stored in the main memory 314, for example.

[0075] Responsive to the segment lengths **S** (Fig. 8) and the three-dimensional location of at least three retro-reflective spheres 525 simultaneously in the field of view of both optical receivers 133, 155, ultrasound sub-system 340 including ultrasound probe 3D position and orientation detector 341 can determine which of the plurality of geometric figures **F** (Fig. 8) is in view of the optical receivers 133, 135. Once the particular geometric figure **F** is identified, the ultrasound sub-system 340 including ultrasound probe 3D position and orientation detector 341 by determining the current orientation of the particular geometric figure **F**, can then further determine the three-dimensional position and the orientation of the optically trackable body 523 of the ultrasound probe with tracker system 140, and thus, the area of interest of a body or patient **P**. The plurality of retro-reflective spheres 525 are assigned three-dimensional coordinate positions with respect to an origin of a coordinate system assigned to the ultrasound probe with tracker system 140 to provide a reference to the origin and a linear direction of each axes of the assigned coordinate system of the ultrasound probe with tracker system 140. The linear direction of each axes of the assigned coordinate system of the ultrasound probe with tracker system 140 coincide with an orientation of each geometric figure **F**, and thus, can define the orientation of the ultrasound probe with tracker system 140. Other methodologies of defining orientation, known by those skilled in the art, can also be used as, for example, the orientation could be defined as the longitudinal, lateral, or some other real or user-defined axes of the ultrasound probe with tracker system 140.

[0076] The ultrasound sub-system **340** including ultrasound probe 3D position and orientation detector **341** can analyze the position and orientation of the identified geometric figure **F** in the field of view of the Infrared 3D Imaging Camera **130** which can then be used to determine the position and orientation of the ultrasound probe **142**. Specifically, responsive to position signals produced by the Infrared 3D Imaging Camera **130** regarding the retro-reflective spheres **525** in the field of view of the Infrared 3D Imaging Camera **130** and segment lengths **S** previously stored of a table of definitions stored in the main memory **314**, or other associated memory in the components **300**, the ultrasound sub-system **340** including ultrasound probe 3D position and orientation detector **341** can determine the three-dimensional position and the orientation (viewing angle) of the ultrasound probe **142**.

[0077] By continuously analyzing the position and orientation of the geometric figures **F**, the position and orientation of the ultrasound probe **142** can be continuously re-determined while the geometric figures **F** remain in the field of view of the Infrared 3D Imaging Camera **130**. The position and orientation of the ultrasound probe **142** can be continuously tracked through various rotations of the ultrasound probe **142** by obfuscating a first of the plurality of retro-reflective spheres **525** as it leaves the field of view of the Infrared 3D Imaging Camera **130** to prevent the first of the plurality of retro-reflective spheres **525** from becoming optically coincident with a second of the plurality of retro-reflective spheres **525**. This can allow ultrasound sub-system **340** including ultrasound probe 3D position and orientation detector **341**, upon determining one of the plurality of geometric figures **F** is exiting view, to thereby replace the one of the plurality of geometric figures **F** positioned in the field of view of the Infrared 3D Imaging Camera **130** with another one of the plurality of geometric figures **F** positioned in the field of view of the Infrared 3D Imaging Camera **130**. This second of the plurality of figures **F**

can then continuously be tracked until replaced with a third of the plurality of figures **F** to provide continuous tracking, for example.

[0078] Referring now to Figure 5, there is illustrated an exploded perspective view of an embodiment of an ultrasound probe with tracker system **140** in an embodiment of the tissue imaging system **100** of Figures 1A and 1B according to the present invention.

[0079] As mentioned, a plurality of optical indicators, such as optically retro-reflective spheres **525**, are connected or mounted to the optically trackable body **523** to form a plurality of desirably dissimilar geometric figures **F**, such as, for example, as can be seen from Fig. 8. A plurality of obfuscators provided by variously positioned obfuscating flanges **527**, obfuscating projections, or other obfuscating obstacles, known to those skilled in the art, optically separate each of the plurality of optical retro-reflective spheres **525** from each other to prevent each of the plurality of retro-reflective spheres **525** from becoming optically coincident with another one of the plurality of retro-reflective spheres **525** when viewed along a viewing path, such as, for example, viewing paths which can extend through adjacent spheres **525**. The retro-reflective spheres **525** can be formed of retro-reflective prisms (not shown), as understood by those skilled in the art, that reflect light that strikes them in the exact opposite direction, for example.

[0080] The optically trackable body **523** correspondingly includes a plurality of separate and spaced apart indicator mounts **729** (Fig. 7) to connect or mount the optical retro-reflective spheres **525** to the optically trackable body **523**. The plurality of optically retro-reflective spheres **525** are adapted to be optically tracked over a subset of possible orientations of the ultrasound probe **142**. The plurality of retro-reflective spheres **525** desirably can have a dissimilar preselected segment length **S** (Fig. 8) between each pair combination. A plurality of combinations of typically at least three of the plurality of retro-reflective spheres **525** can define

a plurality of geometric figures **F**, such as, for example, that geometric figure illustrated in Fig. 8. Further, each sphere **525** in the plurality of the retro-reflective spheres **525** can be positioned to form at least two of the plurality of geometric figures **F** to reduce a selected number of spheres **525** required, for example.

5 **[0081]** The three-dimensional location of the retro-reflective spheres **525** and the orientation of each of the geometric figures can provide three-dimensional positional information and orientation information of the optically trackable body **523**, and thus, the ultrasound probe **142**. Desirably, the geometric figures **F** are readily distinguishable by the Infrared 3D Imaging Camera **130**. The plurality of retro-reflective spheres **525** can be positioned such that by the time
10 one of the geometric figures **F** is no longer visible to the Infrared 3D Imaging Camera **130**, another of the plurality of geometric figures **F** becomes visible to the Infrared 3D Imaging Camera **130**. The position and orientation of each identified geometric figure **F** directly translates to that of the optically trackable body **523**, and thus, the ultrasound probe **142**.

15 **[0082]** Although the plurality of indicators can take the form of other locatable indicators, the optical retro-reflective spheres **525** are desirable as they advantageously can negate the requirement for supplying the ultrasound probe with tracker system **140** with electric power or illumination such as that required by indicators in the form of light emitting diodes or fiber optics, for example. Advantageously, this can also reduce the weight and complication of the ultrasound probe with tracker system **140** and can help prevent the ultrasound probe with
20 tracker system **140** from interfering with an operator or the patient **P** during use of the imaging system **100**. Further, the optical retro-reflective spheres **525** are desirable due to their wide field of view which allows detection at a wide range of viewing angles, as can exceed 180 degrees, for example. This can allow for a smaller trackable body **523** with less required spheres **525**. Also,

associated with the ultrasound probe is a movable object mount 565 as can assist in positioning the ultrasound probe 142. A movable object mounting connector 573 is communicatively associated with the movable object mount 565 for engaging the ultrasound probe 142 with the trackable body 523, for example.

- 5 **[0083]** Referring now to Figures 6, 7 and 8, there are illustrated in Figures 6 and 7 exploded perspective views of embodiments of the optically trackable body 523 of the ultrasound probe with tracker system 140 and, in Figure 8 there is illustrated a perspective view of an embodiment of the optically trackable body 523 of the ultrasound probe with tracker system 140 of a tissue imaging system 100 of Figures 1A according to the present invention.
- 10 **[0084]** As illustrated in Figures 6, 7 and 8, the optically trackable body 523 includes a proximal body end portion 641, a distal body end portion opposite the proximal body end portion 641, a medial body portion positioned between and communicatively connected to and extending between the proximal body end portion 641 and distal body end portion. A plurality of indicator mounts 729 on the medial body portion can be equally radially spaced apart but longitudinally
- 15 staggered in unequal lengths to produce the preselected segment lengths **S** (Fig. 8). Each of the indicator mounts 729 can include an optical indicator mounting recess 747 or other various forms of fasteners or connectors, known to those skilled in the art, for connecting each respective one of the plurality of spheres 525 or other optical indicators to a corresponding plurality of the indicator mounts 729.
- 20 **[0085]** The optically trackable body 523 also includes separating means for optically separating each of the plurality of optical retro-reflective spheres 525 from each other to prevent each of the plurality of retro-reflective spheres 525 from becoming optically coincident with another one of the plurality of retro-reflective spheres 525 when viewed along a viewing path

extending directly through either adjacent pair combination of the plurality of retro-reflective spheres 525. This separating means can serve to enhance optical detection of the plurality of retro-reflective spheres 525 to thereby further enhance determination of the positional location and orientation of the optically trackable body 523, and thus, the ultrasound probe 142.

5 **[0086]** The separating means or separating members can include various forms known and understood by those skilled in the art, but are desirably in the form of a plurality of variously shaped and positioned obfuscators including various forms of flanges, projections, separators, attachments, or other types of obstacles can be positioned between a pair of retro-reflective spheres 525. For example, the optically trackable body 523 can include a plurality of
10 longitudinal medial body portion obfuscating flanges 651 sized and positioned substantially parallel to and spaced apart from the longitudinal axis of the medial body portion of the optically trackable body 523. The plurality of medial body portion obfuscating flanges 651 are of sufficient longitudinal length and radial width to optically separate each retro-reflective sphere 525 of the plurality of retro-reflective spheres 525 mounted to the medial body portion of the
15 optically trackable body 523 from each adjacent retro-reflective sphere 525 of the plurality of retro-reflective spheres 525 also mounted to the medial body portion of the optically trackable body 523. This can significantly reduce a possibility of a retro-reflective sphere 525 of the plurality of retro-reflective spheres 525 mounted to the medial body portion of the optically trackable body 523 from becoming optically coincident with an adjacent retro-reflective sphere
20 525 of the plurality of retro-reflective spheres 525 also mounted to the medial body portion of the optically trackable body 523, when viewed along a preselected (collinear) viewing path, for example.

[0087] Also, the medial body portion obfuscating flanges 651 can be of various geometric designs as long as they are radially short enough so that when observed or viewed such that a reference retro-reflective sphere 525 on the medial body portion of the optically trackable body 523 is "pointing" directly at an observer (e.g. the Infrared 3D Imaging Camera 130; Figures 4 and 8), the medial body portion obfuscating flanges 651 on either side of the reference retro-reflective sphere 525 do not obscure adjacent retro-reflective spheres 525, but are radially and longitudinally long enough so that when observed such that a reference medial body portion obfuscating flanges 651 is "pointing" directly at the observer, the adjacent obfuscating flanges 651 obscure adjacent retro-reflective spheres 525 positioned "behind" the adjacent obfuscating flanges 651, for example.

[0088] Also, the optically trackable body 523 can also include a desirably annular medial body portion obfuscating flange 755 positioned substantially axially parallel with the longitudinal axis of the medial body portion of the optically trackable body 523, such as illustrated in Fig. 8, for example. The radial medial body portion obfuscating flange 755 is positioned and sized to optically separate each retro-reflective sphere 525 of the plurality of retro-reflective spheres 525 mounted to the distal body end portion of the optically trackable body 523 from each adjacent retro-reflective sphere 525 of the plurality of retro-reflective spheres 525 mounted to the medial body portion of the optically trackable body 523. This can prevent each retro-reflective sphere 525 of the plurality of retro-reflective spheres 525 mounted to the distal body portion of the optically trackable body 523 from becoming optically coincident with each retro-reflective sphere 525 of the plurality of retro-reflective spheres 525 mounted to the medial body portion of the optically trackable body 523, when viewed along a preselected viewing path, such as, for example, illustrated in Figure 8. Also, the radial medial body portion

obfuscating flange 755 need not be annular, but can instead be other geometric shapes, as can depend on the use or application, and should not be construed in a limiting sense.

[0089] Because the adjacent spheres 525 are effectively prevented from becoming visually coincident with each other of the spheres 525, and thus, prevented from visually interacting with each other with respect to an outside observer, the spheres 525 forming the various different geometric figures are viewable by the Infrared 3D Imaging Camera 130 such that the Infrared 3D Imaging Camera 130 should generally not find any of the spheres 525 unusable due to coincidence with any of the other spheres 525 in the determination of which of the various different geometric figures **F** is in the field of view of the Infrared 3D Imaging Camera 130. However, more than one different geometric figure **F** can be in the field of view, although normally only one would be selected, for example.

[0090] Also, the optically trackable body 523 can also include an interior mount recess inwardly extending from the proximal body end portion 641 into the medial body portion as can be used to connect the optically trackable body 523 to the ultrasound probe 142, as described (Fig. 5). The interior mount recess is adapted to slidably receive at least portions of a mounting connector, such as, for example, movable object mounting connector 573 (Fig. 5) or a movable object connector 675 of movable object mount 667. Additionally, advantageously mounting connector 675 can include an interior mounting connector recess 677 which can receive the mounting connector 573 (Fig. 5), such that the two mounting connectors 573, 675, can be synergistically implemented together, for example.

[0091] Figures 9 and 10 are the schematic representation of the angular rotation **R** of the x-ray chamber 120 in 360°. The x-ray tube 321 and the digital flat panel detector 323 are housed diametrically opposite to each other with the specimen tray 328 in between them. During

the rotation of the x-ray chamber 120, the specimen tray 328 remains stationary and the x-ray tube 321 and the digital flat panel detector 323 rotate around it. As the rotation happens, the x-rays are generated by the x-ray tube 321 and as they pass through the specimen SP on the specimen tray 328, these x-rays are detected by the digital flat panel detector 323. The specimen SP to be imaged is placed onto the specimen tray 328 through the door 122 on the x-ray chamber 120 as shown in Figure 10.

[0092] The interface display 150 and its display components during ultrasound imaging of the tissue of interest, such as an organ of interest, is shown in Figure 11. A live ultrasound display window 1120 shows the live ultrasound image as the patient's P's area of interest is being scanned. The probe orientation 1130 in degrees and the probe position 1131 in an x, y, and z coordinate system are displayed for the specific live ultrasound image 1122. The user is provided tools to draw 1140 and erase 1141 the contours in the area of interest (for example: a tumor) 1123. A measurement tool 1142 allows the user to perform measurements on the 2D ultrasound image. The display allows the user to review the scanned ultrasound images using the left arrow 1144 and the right arrow 1143 buttons. A 3D volume of the ultrasound is displayed in display window 1110 along with the contoured structures 1113. The measurements of the structure that includes the length [X] 1151, width [Z] 1153, height [Y] 1152, and volume 1154 are displayed to the user. A 3D axis 1114 is provided that can help in visualization of the orientation of the structure 1113.

[0093] Once the tissue specimen SP (for example: a tumor) is extracted from the patient P, and imaged in the x-ray chamber 120, the comparison of the 3D volume image of the extracted specimen SP and the 3D ultrasound based contoured structure 1113 are displayed for comparison as shown in Figure 12A and 12B. A volume comparison window 1210 in Figure

12A shows the side-by-side comparison of the contoured 3D ultrasound structure **1113** in the display window **1110** illustrating the tissue of interest in the body and the extracted specimen **SP** illustrated in an X-ray 3D volume image displayed in a window **1211**. Figure 12A also displays a volume **1151**, a length [X] **1152**, a width [Z] **1154**, and a height [Y] **1153** of the contoured 3D ultrasound structure **1113** tissue of interest in the body. Figure 12A also displays a volume **1251**, a length [X] **1252**, a width [Z] **1254**, and a height [Y] **1253** of the 3D specimen **SP** imaged via the x-ray system. A display window **1220** in Figure 12B displays an image illustrating the fused contoured ultrasound 3D structure **1113** and the extracted tissue specimen **SP** imaged via the X-ray system superimposed as a fused image **1223** in a fusion window **1221**. A difference in a volume **1261**, a length [X] **1262**, a width [Z] **1264**, and a height [Y] **1263** between the contoured ultrasound 3D structure **1113** and the extracted tissue specimen **SP** is displayed to the user.

[0094] Figure 15A and 15B are examples of the fusion analysis. Figure 15A shows a fused structure image **1223a** with **1510** indicating the ultrasound volume of the contoured ultrasound 3D structure and **1520** indicating the x-ray volume of the extracted tissue specimen **SP**. As illustrated in Figure 15A, the imaging system **100** has determined and illustrates on the interface display **150** that there is no measurable difference in the two volumes **1510** and **1520** as illustrated in the measurements of a difference volume **1261**, a length [X] **1262**, a height [Y] **1263**, and a width [Z] **1264** with respect to the volumes **1510** and **1520** as they are substantially aligned on top of each other. However, in Figure 15B a difference in the fused volume **1223b** between a contoured 3D ultrasound structure **1530** and 3D volume **1540** of an extracted specimen **SP** imaged via X-ray imaging is visible. Image **1550** shows an overall difference in volume wherein images **1552**, **1554**, and **1556** show the specific areas of volume differences. The quantitative values of the differences between the contoured 3D ultrasound structure **1530**

and the 3D volume **1540** of the extracted specimen **SP** are also displayed in the interface display **150** as a difference volume **1261**, a difference length [X] **1262**, a difference width [Z] **1264**, and a difference height [Y] **1263**.

[0095] Referencing Figures 13 and 14, there is illustrated schematic diagrams of the x-ray system while performing imaging of the biopsy samples, such as to determine if the tissue of interest is to be removed, for example. The biopsy samples are imaged with the x-ray chamber **120** rotated at an angle of 90° . The x-ray tube **321** is positioned over the specimen tray **328** and the digital flat panel detector **323** is positioned below the specimen tray **328**, such as illustrated in Figure 13, for example. The biopsy samples **BSP** are placed into the specimen tray **328** through the door **122** in the x-ray chamber **120**. The x-rays are generated by the x-ray tube **321** and as they pass through the biopsy samples **BSP** on the specimen tray **328**, the x-rays are detected by the digital flat panel detector **323** and a detected image **IBSP**.

[0096] As an example of an embodiment of a process for imaging a specimen **SP** using the imaging system **100** is illustrated by an exemplary process workflow **1600**, such as for performing a Lumpectomy, and its analysis is schematically represented in flowchart of the process in Figure 16A. The first part of the process is Ultrasound Imaging for Tumor Detection: The ultrasound probe with tracker system **140** is connected to the imaging system **100** and is calibrated in the operating room before imaging the patient **P** as part of step **1602**. Patient **P** is wheeled into the operating room and is laid on the Operating Table **T** in the supine position in step **1604**. The physician images the breast, such as at location **L1** (or any other organ or location of interest **L2**, **L3**) using the ultrasound probe in the workflow step **1606**. Multiple ultrasound images in step **1610** are acquired of the breast using the ultrasound probe **142** in different positions and orientations and the ultrasound probe **142** position and orientation are

recorded into the imaging system 100 during step 1608. The physician draws the contours on the tissue of interest, such as a tumor, on the displayed 2D ultrasound images in step 1612, such as of the breast as shown in area of interest 1123. In step 1614, using the position and orientation of the ultrasound image along with the contoured structures, a linear interpolation algorithm, such as known to one skilled in the art, is used to create the 3D volume of the breast and the contoured structures as shown in Figure 11 in the contoured structures 1113. The imaging system 100 displays on the interface display 150 the measurements of the contoured area of interest, such as a tumor, which is the height [Y] 1152, the length [X] 1151, the width [Z] 1153, and the volume 1154. The second part of the process 1600 is to perform tissue extraction (for example: a Lumpectomy). A surgeon performs a lumpectomy on the patient P in step 1618 and places the specimen SP in the X-ray chamber 120 of the imaging system 100 as part of the workflow step 1620. The third part of the process 1600 is X-Ray Imaging of the specimen SP. In workflow step 1622, x-ray imaging of the specimen SP is performed as described in Figures 9 and 10. As the x-ray tube 321 rotates along with the digital flat panel detector 323 around the specimen SP, a 3D volume of the specimen SP is displayed to the physician in the display window 1211 in step 1624, as, for example, by using a back projection algorithm, such as known to one skilled in the art. The fourth part in the process 1600 is the analysis of the specimen SP. In workflow step 1626 a comparison of the contoured structures and the extracted specimen SP is performed to determine if the correct volume for the SP has been extracted. The measurements of the contoured structure 1113 and the specimen SP x-ray volume are displayed as shown in Figure 12A and the differences in the dimension and volume measurements are displayed as shown in Figure 12B. The physician then compares and checks the margins of the 3D volumes along with their measurements to determine if enough tissue was extracted.

Referring now to Figure 16B, there is illustrated an process **1650** for a workflow for imaging biopsy samples. In a first step **1652** of the process **1650**, the patient **P** is wheeled into the operating room for biopsy procedure. In a next step **1654**, as per the workflow **1900** as described in Figure 19 and using the imaging system **100** arranged as illustrated in Figure 17, imaging of the tissue of interest, such as a breast, is performed using the ultrasound probe and tracker system **140**. Then, in next step **1656**, Biopsy samples **BSP** from the tissue are extracted under ultrasound guidance. In workflow step **1658**, the extracted biopsy samples **BSP** are placed into the specimen tray **328**. Once all the biopsy samples **BSP** are placed into the specimen tray **328**, then in step **1660** the specimen tray **328** is placed into the x-ray chamber **120** and the x-ray imaging is performed as described in Figure 13 and Figure 14. In the last step **1662** of the workflow, a needle path as shown in Figure 18C and the x-ray images of the biopsy samples **BSP** are visualized to ensure that the biopsies are extracted from the correct location in the body.

[0097] Referring to Figures 17, 18A and 18B, Figure 17 is a schematic representation of performing a biopsy or placing a seed marker under ultrasound guidance using the imaging system **100**. Ultrasound images of the tissue of interest, such as an organ (for example: the breast), are acquired using the ultrasound probe with the tracking system **140** and the area of interest (for example: a tumor) is contoured and display as contoured image **1850** as part of an ultrasound image **1822** and a 3D volume **1860** of the contoured structure is created and displayed in the display window **1110** on the interface display **150**, as shown in Figure 18A. A needle system **1700** is a generalized representation of various needle systems that can be used for biopsy or for placing a seed marker **1760** into the area of interest **1750**. The needle system **1700** includes a holder **1710** for a needle **1720** and includes the needle **1720**. The needle **1720** is inserted into tissue **1730** under ultrasound guidance using the imaging system **100**. The needle

1720 that is inserted into the tissue 1730 is displayed in a live ultrasound image 1822 as a needle image 1820 in Figure 18A. A 3D representation of the needle image is also shown as numeral 1822 in the display window 1110 in Figure 18A. As the needle 1720 is inserted into the tissue 1730 under ultrasound guidance, the needle image 1820 is displayed along with an image orientation 1872 and an image position 1874 along with the ultrasound image 1822 as illustrated in Figure 18B. By clicking on a mark biopsy button 1876 the physician is able to mark the needle path on the needle image 1820 in the ultrasound image display window 1120. Once the needle image 1820 is marked in the 2D ultrasound image, the 3D representation of the needle also indicated by the numeral 1822 is displayed in the 3D window 1110. The physician can mark multiple needle paths as the needle 1720 is inserted into the tissue 1730. To review the needle paths, the physician can click on a review biopsy button 1878 and the images 1120 and 1110 are displayed in the interface display 150 as shown in Figure 18C. The display 1120 shows 2D ultrasound image 1822 with a plurality of various needle paths, such as needle paths 1820a, 1820b, 1820c, and 1820d. The needle paths are also displayed in 3D as 3D needle paths, such as needle paths 1822a, 1822b, 1822c, 1822d and 1822e, as shown in the display 1110.

[0098] Figure 19 shows a workflow process 1900 for Biopsy and Seed Localization. As a first step 1902 of the workflow, the patient P is wheeled into the Operating Room. In step 1904 ultrasound imaging of tissue of interest, such as an organ (for example: the breast), is performed using the ultrasound probe with tracker 140. Multiple images of the breast are acquired along with the ultrasound probe position and orientation by the imaging system 100, as previously described. Then, step 1906 is a decision step as part of the workflow process 1900 to decide if a biopsy or a seed marker placement/localization is to be performed. If biopsy is to be performed, the process proceeds to step 1910 and in this step a 2D live ultrasound image of the

breast is displayed along with the image orientation **1872** and image position **1874** of the image **1822** as shown in Figure 18B. In step **1930**, a 3D volume **1860** of the ultrasound images acquired in step **1904** is displayed in the display window **1110** as shown in Figure 18B. Then, in step **1920**, the biopsy needle **1720** is inserted into the breast to extract a biopsy sample. The
5 needle is visualized in the live 2D ultrasound image as shown in display window **1120** as ultrasound image **1820** as shown in Figure 18B. Then in step **1922**, the physician marks the biopsy needle path and the needle path is stored in a memory, such as the main memory **314**, in the imaging system **100**. As the physician performs multiple biopsies on the same patient **P** for the same area of interest, the physician marks each needle path and these needle paths are stored
10 in a memory, such as the main memory **314**, of the imaging system **100**. From step **1922**, the process proceeds to step **1932**, such that as soon as the needle path is marked in a 2D ultrasound image, the imaging system **100** displays the needle path in the 3D display window **1110** as the needle image **1822** as shown in Figure 18B. Then if the physician desires to review the biopsy needle paths, the process proceeds to step **1924** to review the needle paths by clicking on the
15 Review Biopsy button **1878** in Figure 18B, and the physician can then review and verify the biopsy needle paths for all the biopsies performed as shown in Figure 18C. However, in the decision step **1906**, if a seed placement/localization is to be performed, the process then proceeds to step **1940** to display a 2D live ultrasound image of the breast along with the image orientation **1872** and the image position **1874** of the ultrasound image **1822** as shown in Figure 18B. Also,
20 in step **1950**, a 3D volume of the ultrasound images acquired in step **1904** is displayed in the display window **1110** as shown in Figure 18B. Then in step **1942**, the needle **1720** with seed marker **1760** is inserted into the breast and visualized in a 2D live ultrasound image similar to that visualized for biopsy in display window **1120** as needle image **1820** as in Figure 18B. The

physician marks the needle path as done in the step 1922. Then in step 1952, as soon as the physician marks the needle path in the 2D ultrasound image 1822, the needle path is then visualized as needle image 1822 in the 3D display window 1110 as described in step 1932. Then in step 1946, once the seed marker 1760 is placed into the desired location in the tissue 1730 under ultrasound guidance provided by the imaging system 100, the physician marks the seed marker 1760 location in the 2D ultrasound image 1822 visualized in the display window 1120, as described in Figure 18B. Then, in step 1956, the seed marker 1760 is visualized in 3D display window 1110.

[0099] As evident from the foregoing, the imaging system 100 can be used for a plurality of various treatments, procedures, or other therapeutic purposes, such as, for example, for prostate imaging and biopsy, as well as can be used for tissue extraction from a body. Also, the imaging system 100 can be used in addition to humans, can also be used for various research and medical application for animals, reptiles and other organisms, for example.

[00100] It is to be understood that the present invention is not limited to the embodiments described above, but encompasses any and all embodiments within the scope of the following claims.

I CLAIM:

1. A tissue imaging system, comprising:

an x-ray subsystem comprising an x-ray chamber, an x-ray beam generator and controller, an x-ray angle controller and an x-ray analysis processor and memory, the x-ray chamber including an x-ray tube, a digital flat panel detector and a specimen tray, wherein the x-ray analysis processor and memory includes a two dimensional (2D) and a three dimensional (3D) x-ray image generator and a processor for measurement and analysis of the x-ray images;

an ultrasound subsystem including an ultrasound probe with tracker system, an infrared 3D imaging camera, an ultrasound probe 3D position and orientation detector, an ultrasound beamformer, and an ultrasound analysis processor and memory, the ultrasound analysis processor and memory including an ultrasound 2D image generator, an ultrasound position and angle calculator, and an ultrasound 3D volume generator including a processor for measurement and analysis; and

a processor controller system including an image fusion generator including a fusion processor and memory to fuse a 3D ultrasound volume image and a 3D x-ray volume image of a specimen for measurement and analysis.

2. The tissue imaging system according to claim 1, wherein:

the x-ray chamber rotates 360° around its axis, and

the x-ray tube and the digital flat panel detector rotate 360° around the stationary specimen tray inside the x-ray chamber.

3. The tissue imaging system according to claim 1, wherein:

the ultrasound subsystem creates a 3D volume of the ultrasound image and contoured structures of an area of interest based on the ultrasound image, ultrasound probe orientation and the ultrasound probe position.

5 4. The tissue imaging system according to claim 3, wherein:

the Image Fusion Generator fuses the 3D volume of the contoured structure of the area of interest and the 3D volume of the specimen.

5. The tissue imaging system according to claim 4, wherein:

10 the x-ray subsystem generates the 3D volume of the specimen placed in the specimen tray of the x-ray chamber.

6. The tissue imaging system according to claim 5, wherein:

the Image Fusion Generator fuses the 3D volume of the contoured structure of the area of interest and the 3D volume of the specimen and generates a 3D volume illustrating a combined 3D volume of the contoured structure of the area of interest and the 3D volume of the specimen to provide measurements relating to a volume, a height, a length and a width of the contoured structure and the extracted specimen.

20 7. The tissue imaging system according to claim 6, wherein:

a difference in a 3D volume, height, length and width between the generated combined 3D volume of the specimen and the 3D volume of the contoured structure from the generated combined 3D volume formed by the fused 3D ultrasound volume image and the 3D x-ray

volume image are determined for quantitative analysis by the tissue imaging system.

8. A tissue imaging system, comprising:

an x-ray subsystem to generate a two dimensional (2D) x-ray image and a three
5 dimensional (3D) x-ray volume image of a specimen for measurement and analysis of the x-ray
images;

an ultrasound subsystem including an ultrasound probe and an imaging camera to
determine a position and orientation of a contoured structure in an area of interest that includes
the specimen and to generate an ultrasound 2D image of the contoured structure in an area of
10 interest and an ultrasound 3D volume image of the contoured structure for measurement and
analysis; and

an image fusion generator including a fusion processor to fuse the ultrasound 3D volume
image of the contoured structure and the 3D x-ray volume image of the specimen for
measurement and analysis.

15

9. The tissue imaging system according to claim 8, wherein the x-ray subsystem comprises:

an x-ray chamber, an x-ray tube and a digital flat panel detector, wherein

x-ray chamber rotates 360° around its axis, and

the x-ray tube and the digital flat panel detector rotate 360° around a stationary

20

specimen tray inside the x-ray chamber.

10. The tissue imaging system according to claim 9, wherein:

the x-ray subsystem generates the 3D x-ray volume image of the specimen placed in the
specimen tray of the x-ray chamber.

11. The tissue imaging system according to claim 8, wherein:

the ultrasound subsystem creates the ultrasound 3D volume image of the contoured structure based on the generated ultrasound 2D image.

5

12. The tissue imaging system according to claim 8, wherein:

the image fusion generator fuses the ultrasound 3D volume image of the contoured structure with the 3D x-ray volume image of the specimen to create a combined 3D volume image.

10

13. The tissue imaging system according to claim 12, wherein:

the combined 3D volume image generated by the image fusion generator provides measurements relating to a volume, a height, a length and a width of the contoured structure and the specimen.

15

14. The tissue imaging system according to claim 13, wherein:

a difference in 3D volume, the height, the length, and the width between the ultrasound 3D volume image of the contoured structure and the 3D x-ray volume image of the specimen are determined from the combined 3D volume image for quantitative analysis by the tissue imaging system.

20

15. A method for tissue imaging in a tissue imaging system, comprising the steps of:

generating a two dimensional (2D) x-ray image and a three dimensional (3D) x-ray volume image of a specimen for measurement and analysis of the x-ray images;

generating an ultrasound 2D image of a contoured structure in an area of interest that includes the specimen and an ultrasound 3D volume image of the contoured structure for measurement and analysis; and

combining the ultrasound 3D volume image of the contoured structure and the 3D x-ray volume image of the specimen to provide a combined 3D volume image for measurement and analysis.

16. The method for tissue imaging in a tissue imaging system according to claim 15, further comprising the step of:

determining a volume, a height, a length and a width of the contoured structure and the specimen from the combined 3D volume image.

17. The method for tissue imaging in a tissue imaging system according to claim 16, further comprising the step of:

determining a difference in 3D volume, the height, the length, and the width between the ultrasound 3D volume image of the contoured structure and the 3D x-ray volume image of the specimen for quantitative analysis by the tissue imaging system.

18. A method for ultrasound imaging in a biopsy or a seed localization procedure, comprising the steps of:

generating a two dimensional (2D) live ultrasound image of a tissue of interest;

generating a three dimensional (3D) ultrasound volume image from the live 2D ultrasound image of the tissue of interest; and

displaying with the generated two dimensional (2D) live ultrasound image and with the

generated three dimensional (3D) ultrasound volume image an image of at least one needle to provide a representation of an angle and a position of the at least one needle and at least one needle path in relation to the tissue of interest for the biopsy or seed localization to provide a representation of an angle and a position of the at least one needle for the biopsy or the seed
5 localization in relation to the tissue of interest.

19. The method for ultrasound imaging in a biopsy or a seed localization procedure according to claim 18, further comprising the steps of:

positioning a seed marker in a location in the tissue of interest using ultrasound guidance
10 based on the generated 2D live ultrasound image; and

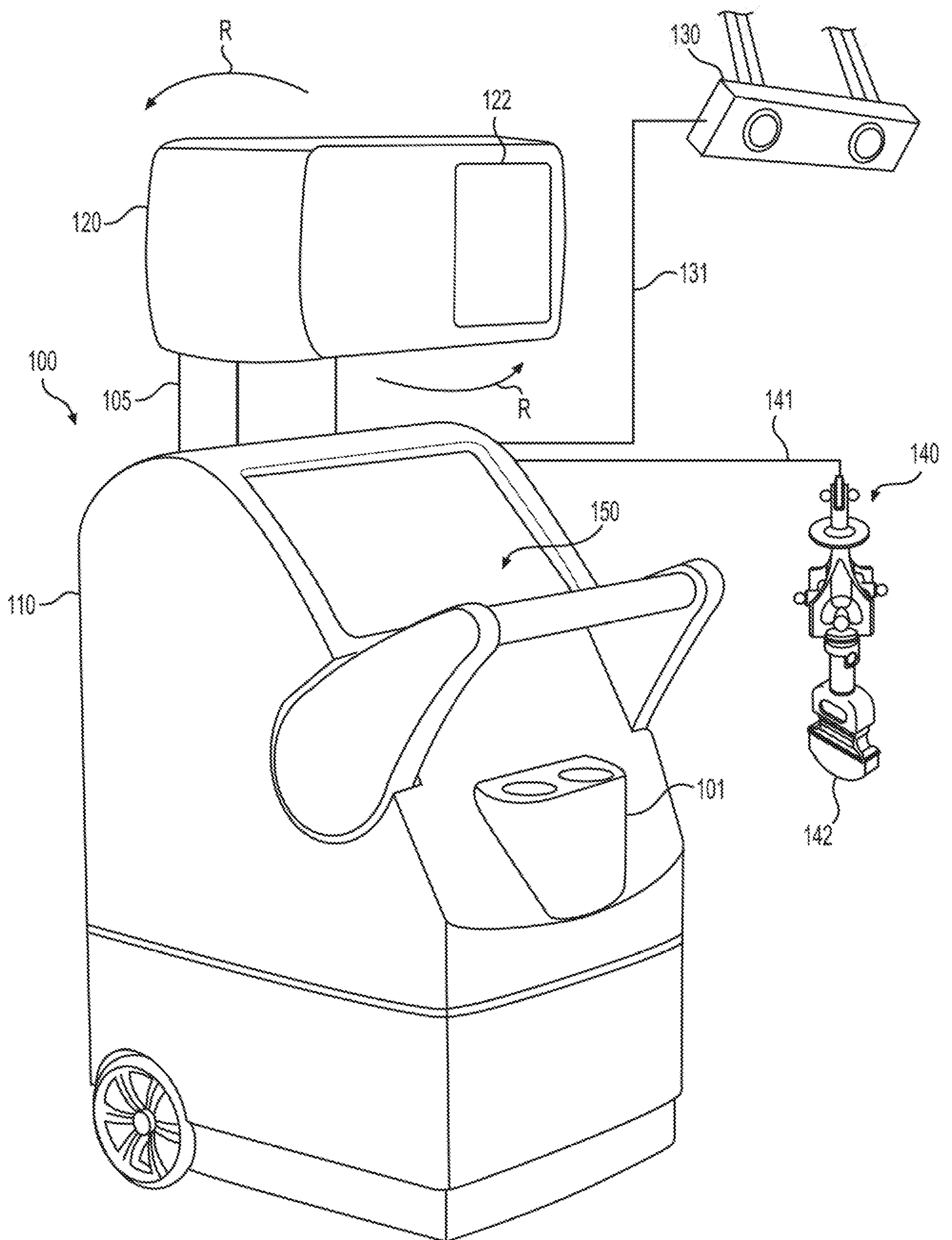
marking the positioned seed marker in the generated 2D ultrasound image in relation to the tissue of interest.

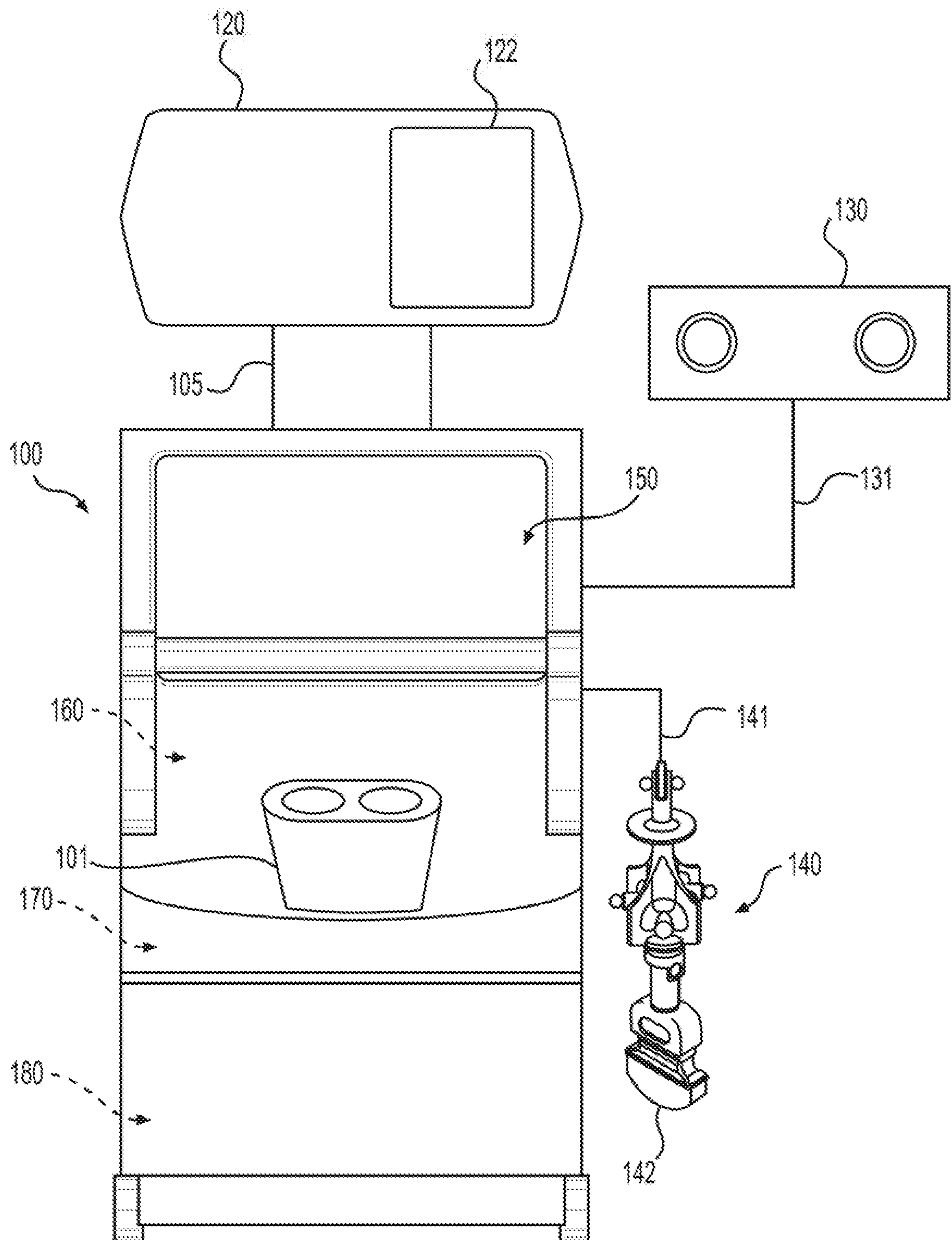
20. The method for ultrasound imaging in a biopsy or a seed localization procedure
15 according to claim 19, further comprising the step of:

displaying the positioned seed marker in the generated 3D ultrasound volume image of the tissue of interest.

21. The method for ultrasound imaging in a biopsy or a seed localization procedure
20 according to claim 18, further comprising the step of:

displaying in the generated 2D live ultrasound image and in the generated 3D ultrasound volume image a plurality of needle paths in relation to the tissue of interest for each of a plurality of biopsies.

**FIG. 1A**

**FIG. 1B**

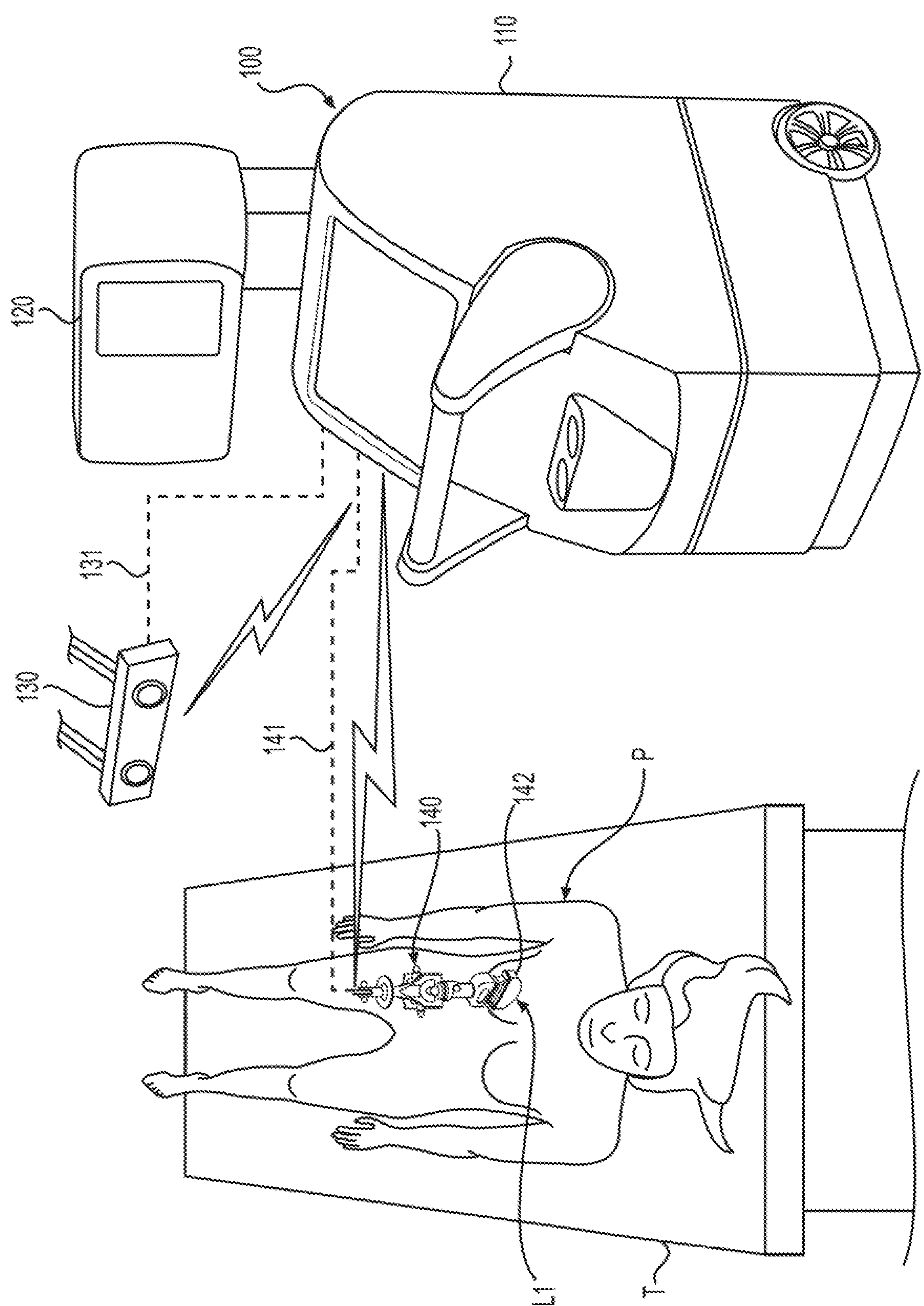
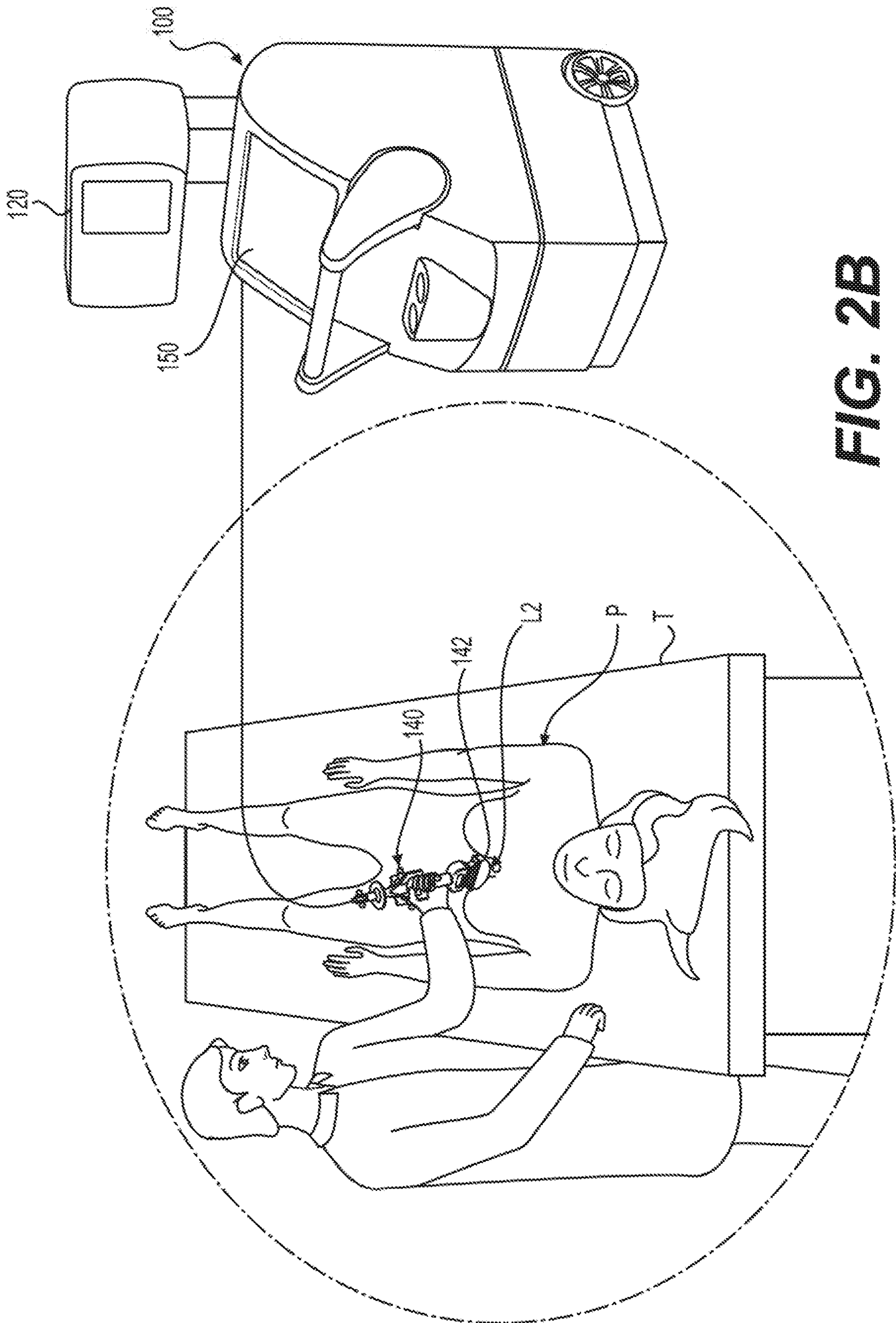
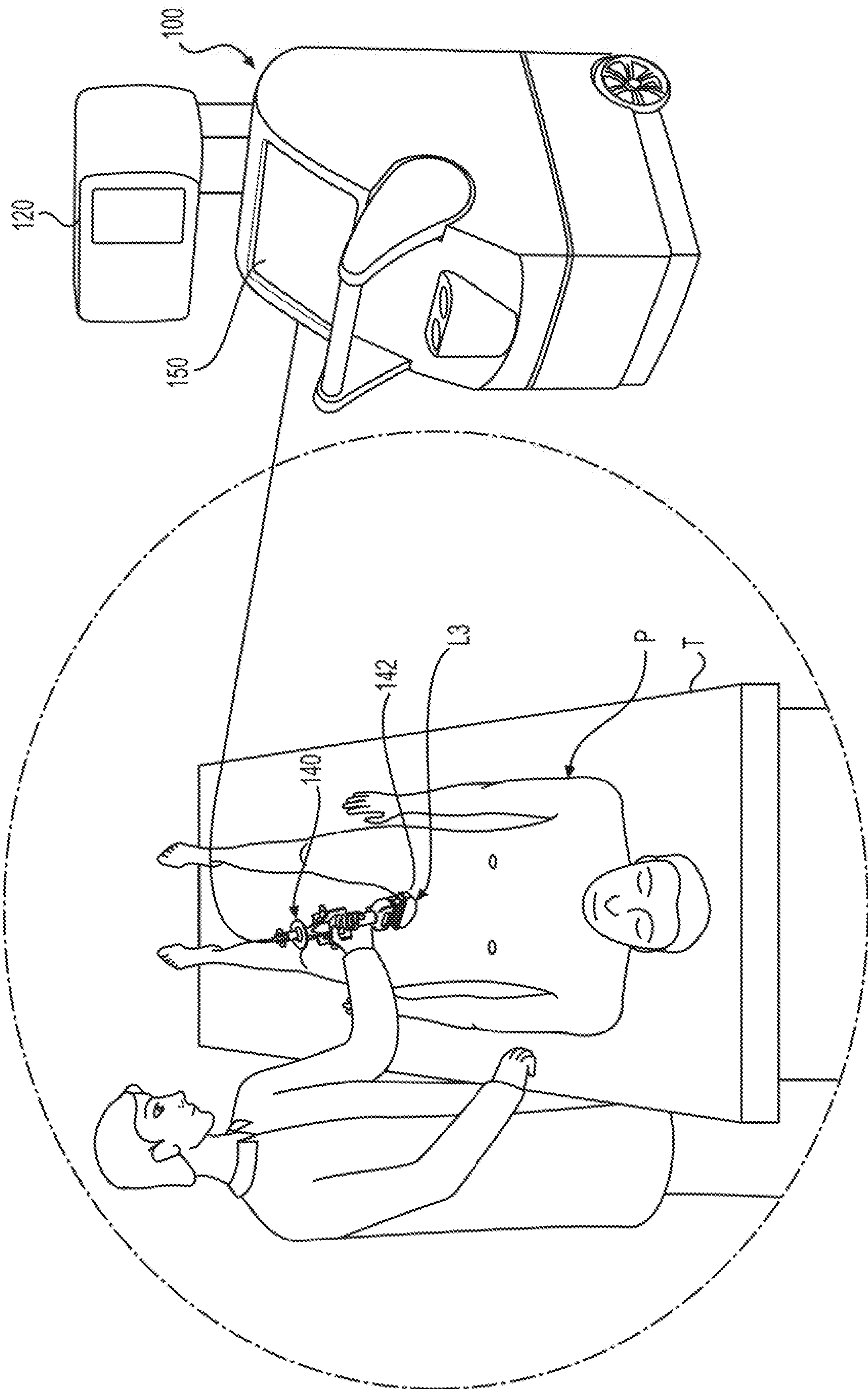
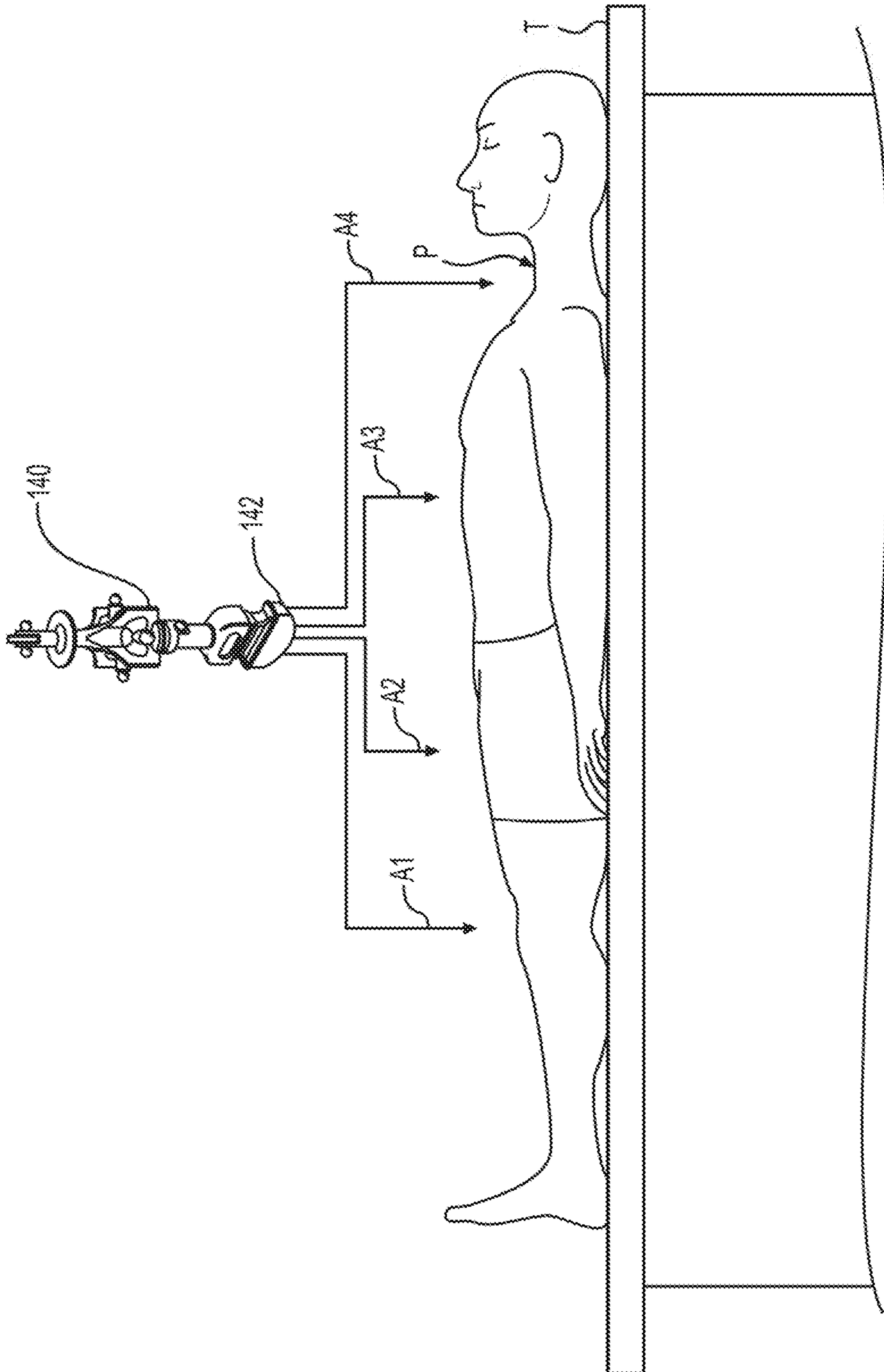
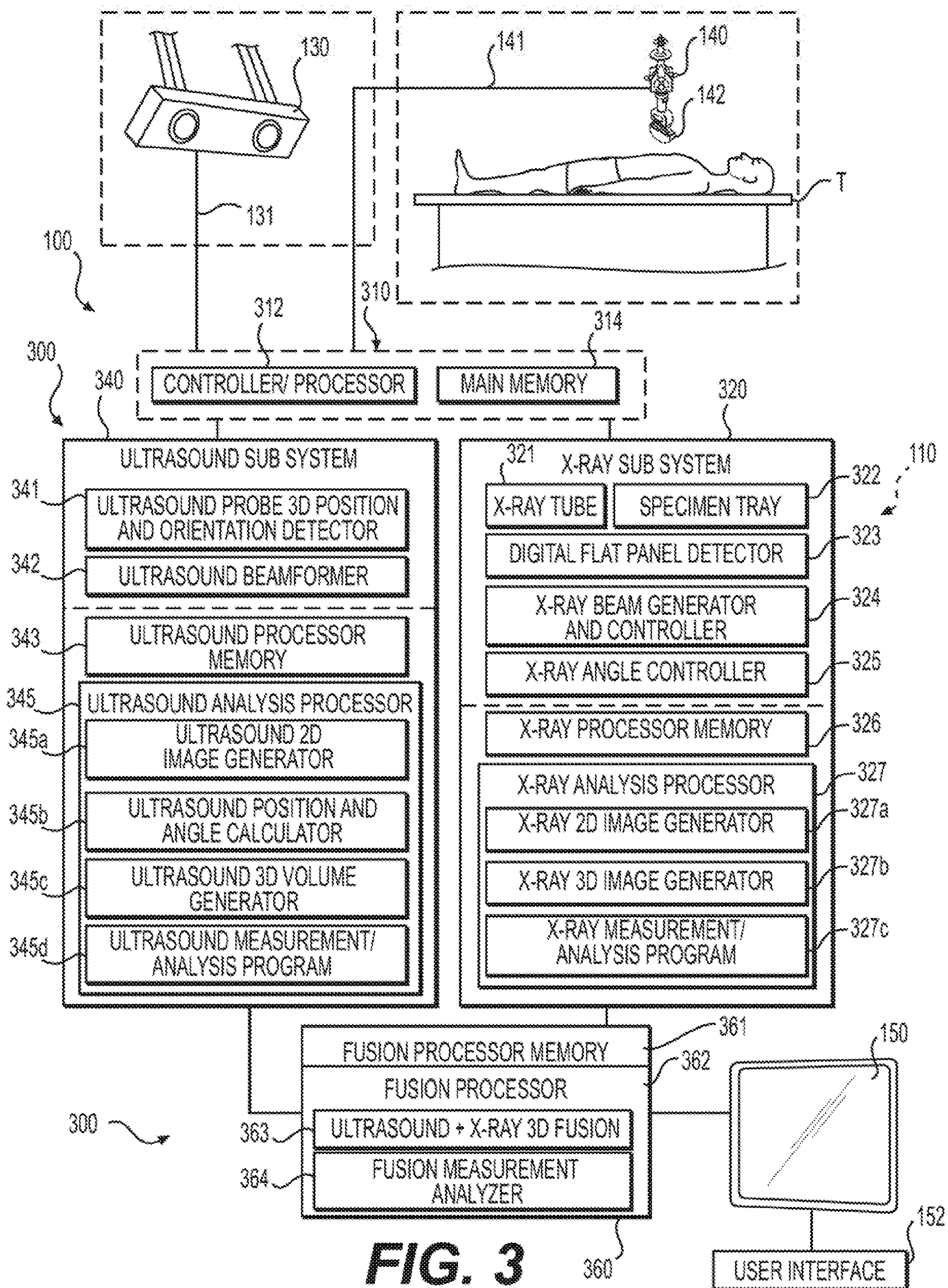


FIG. 2A



**FIG. 2C**

**FIG. 2D**

**FIG. 3**

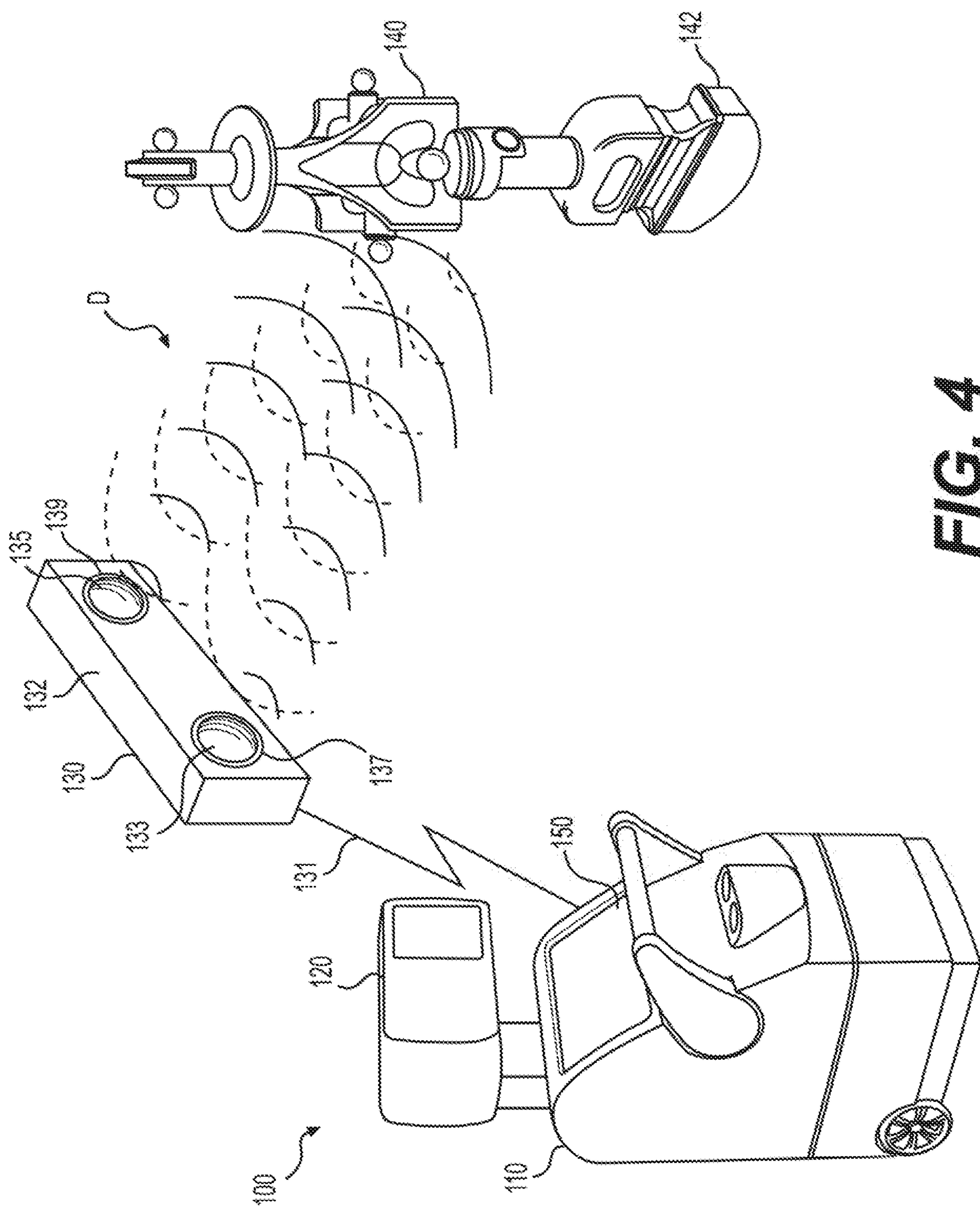
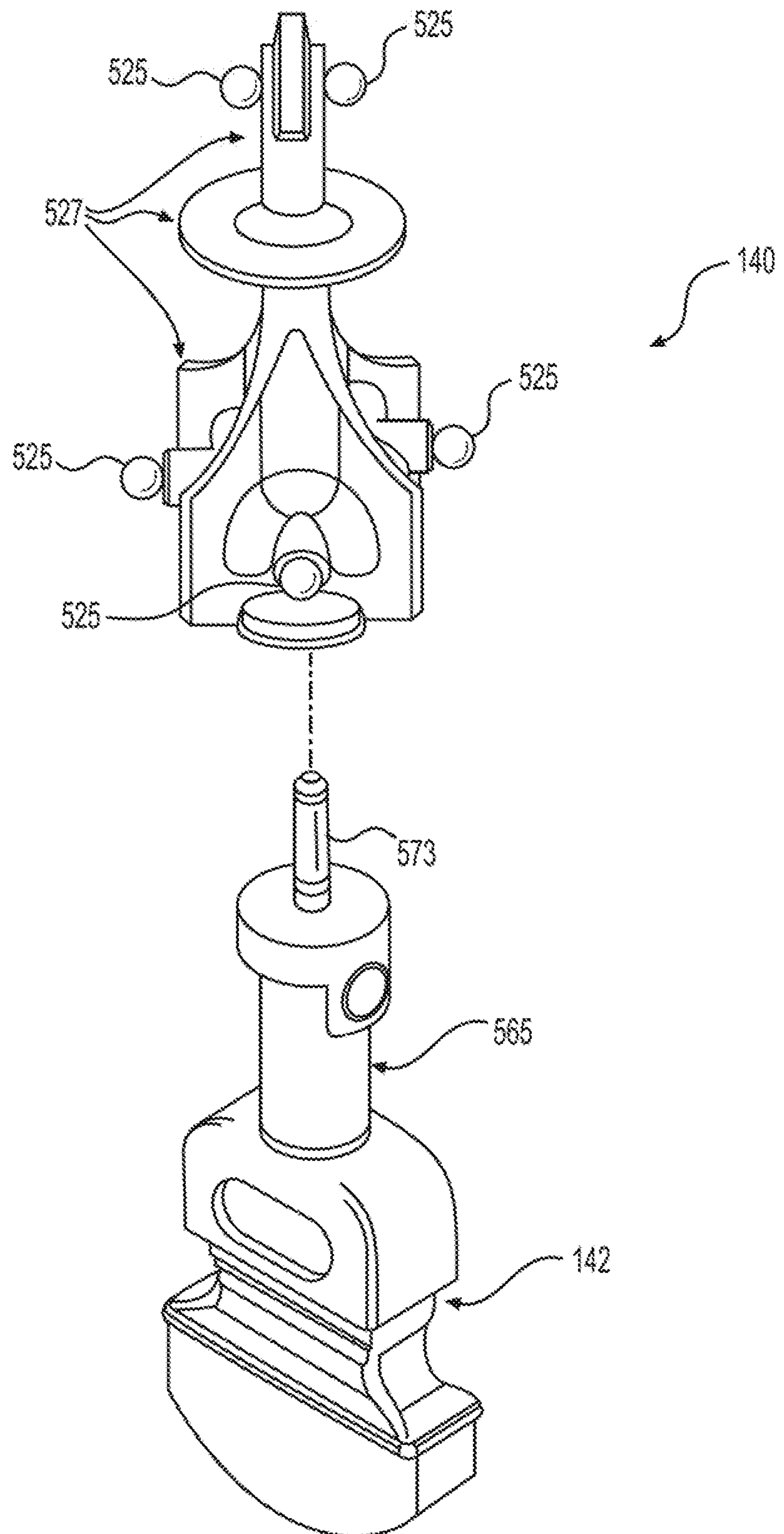
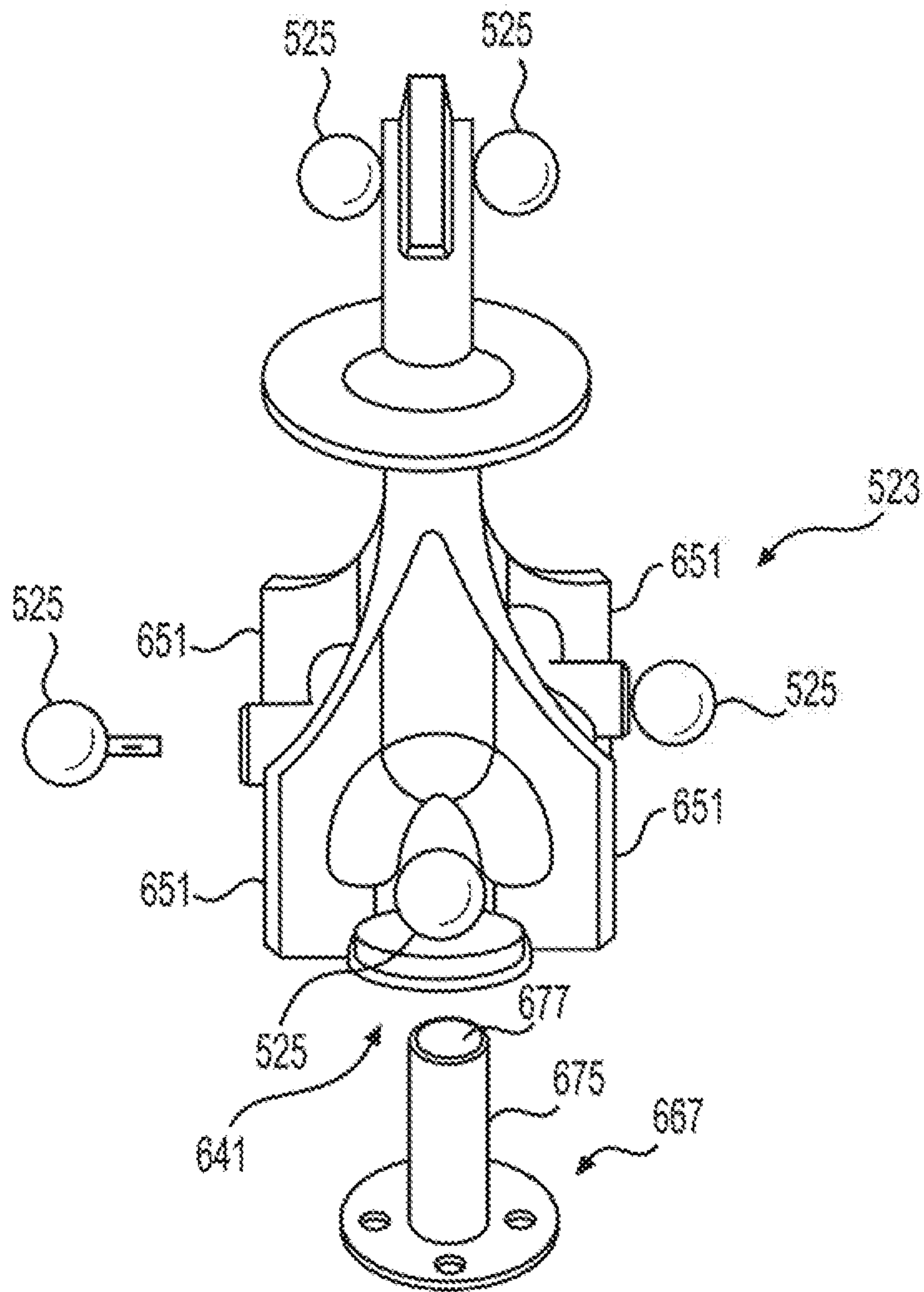
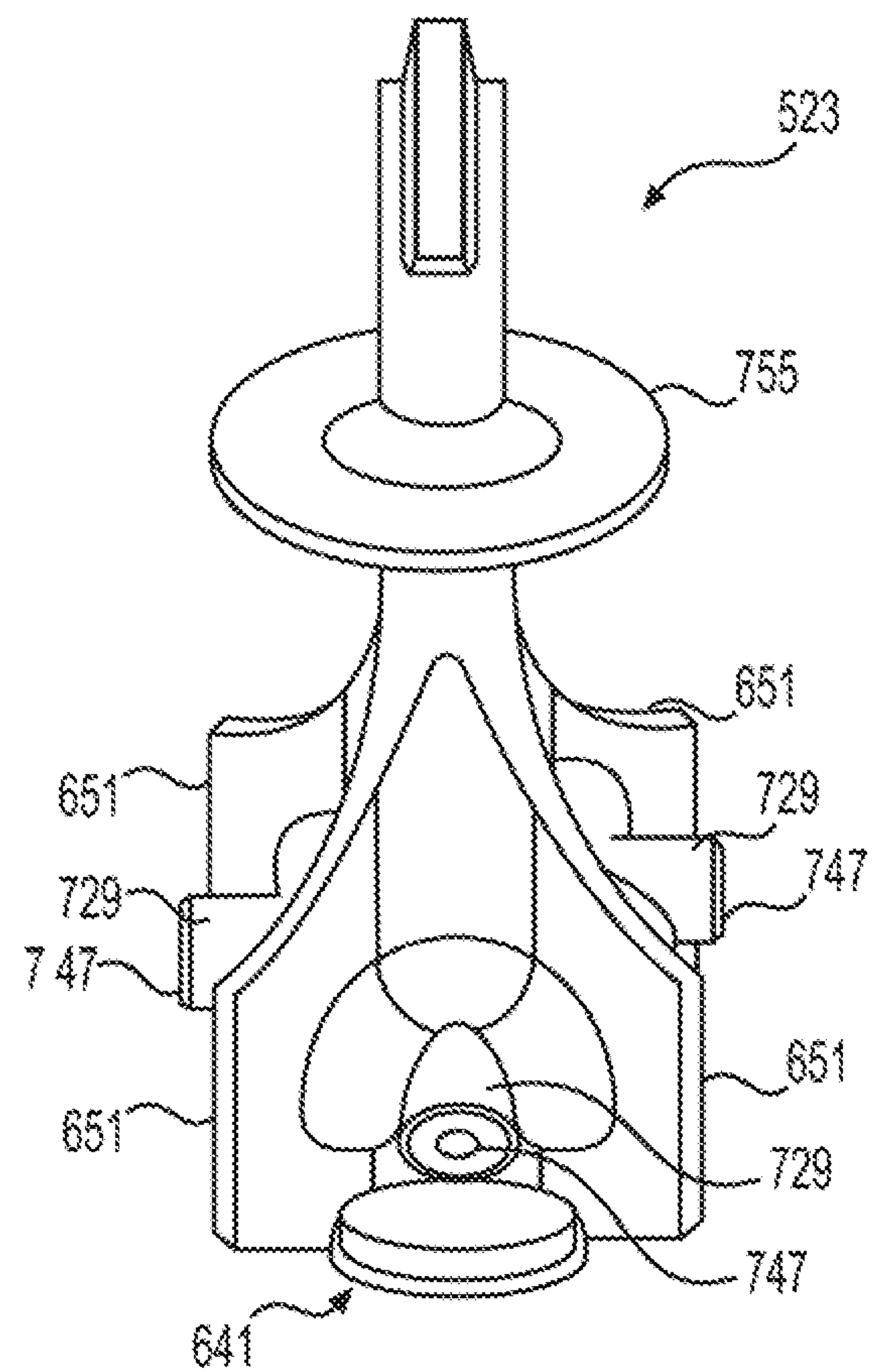
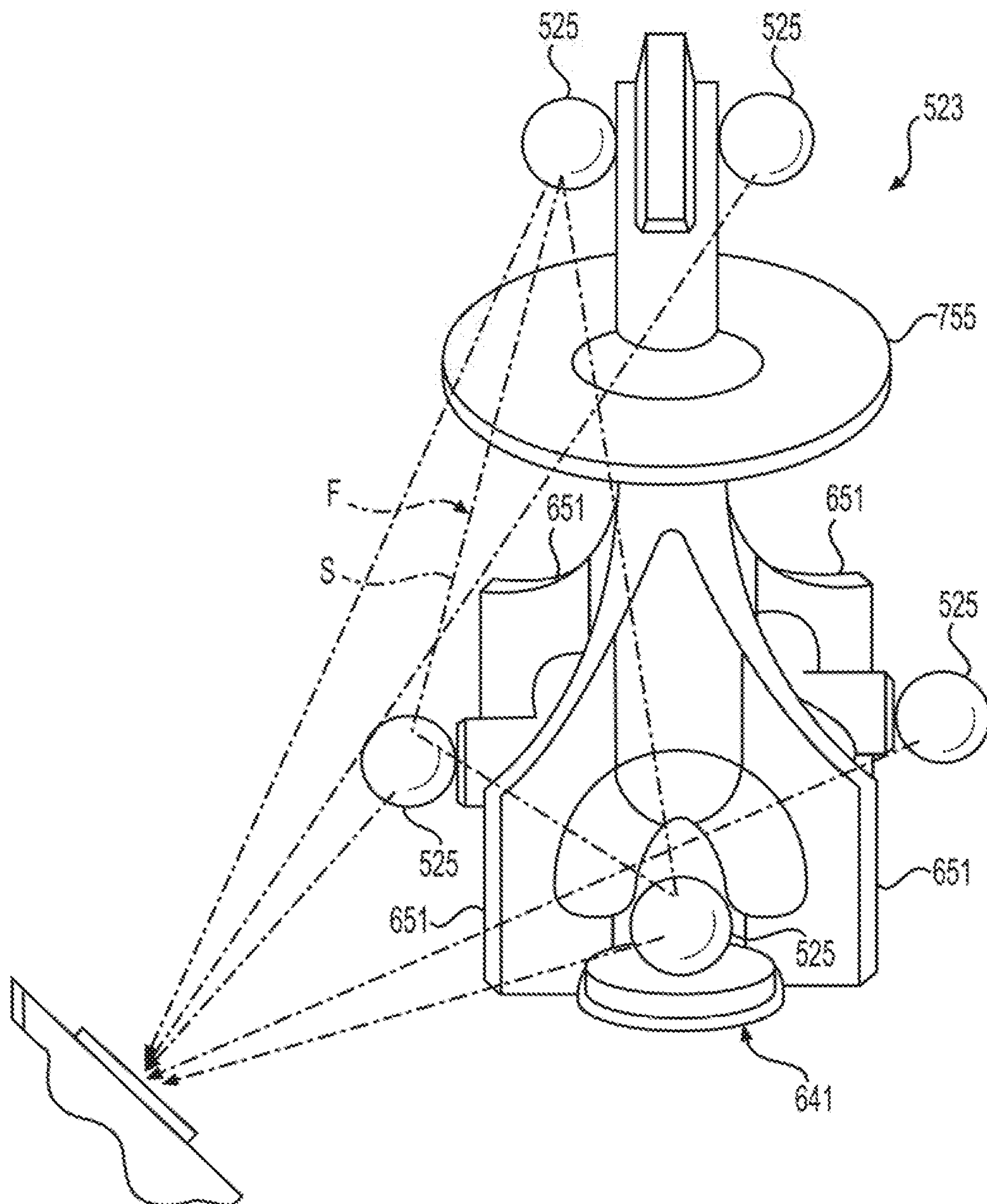
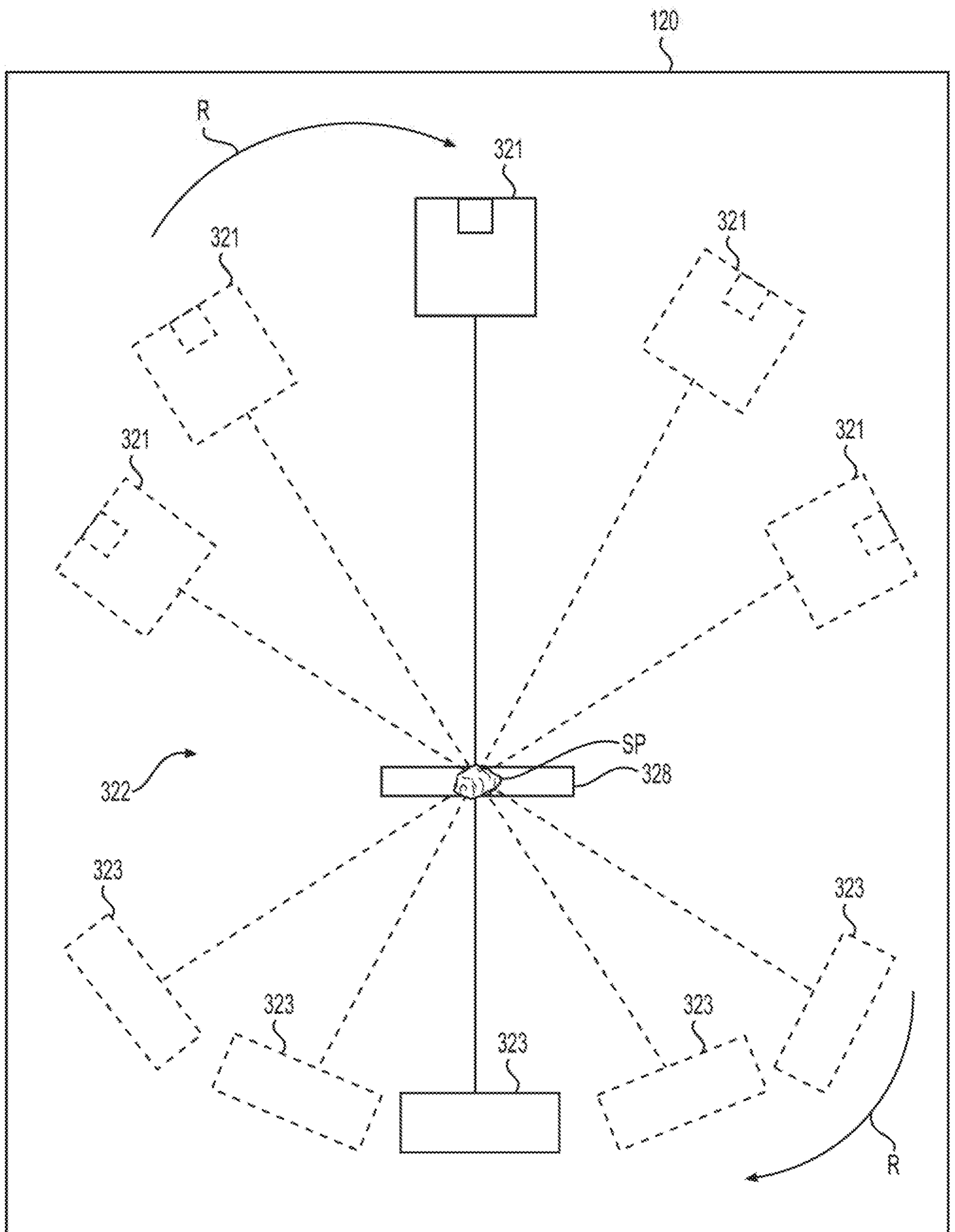


FIG. 4

**FIG. 5**

**FIG. 6****FIG. 7**

**FIG. 8**

**FIG. 9**

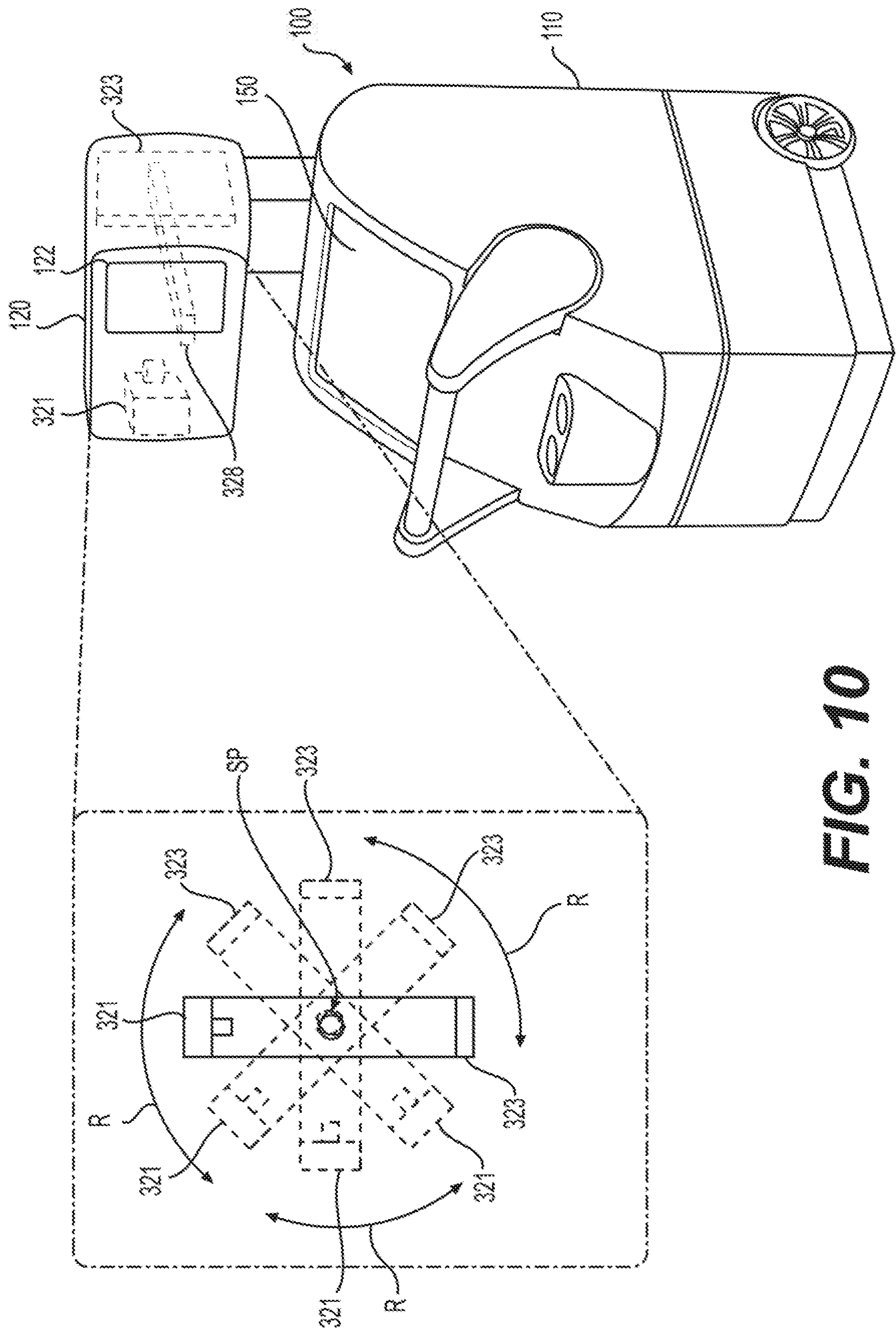


FIG. 10

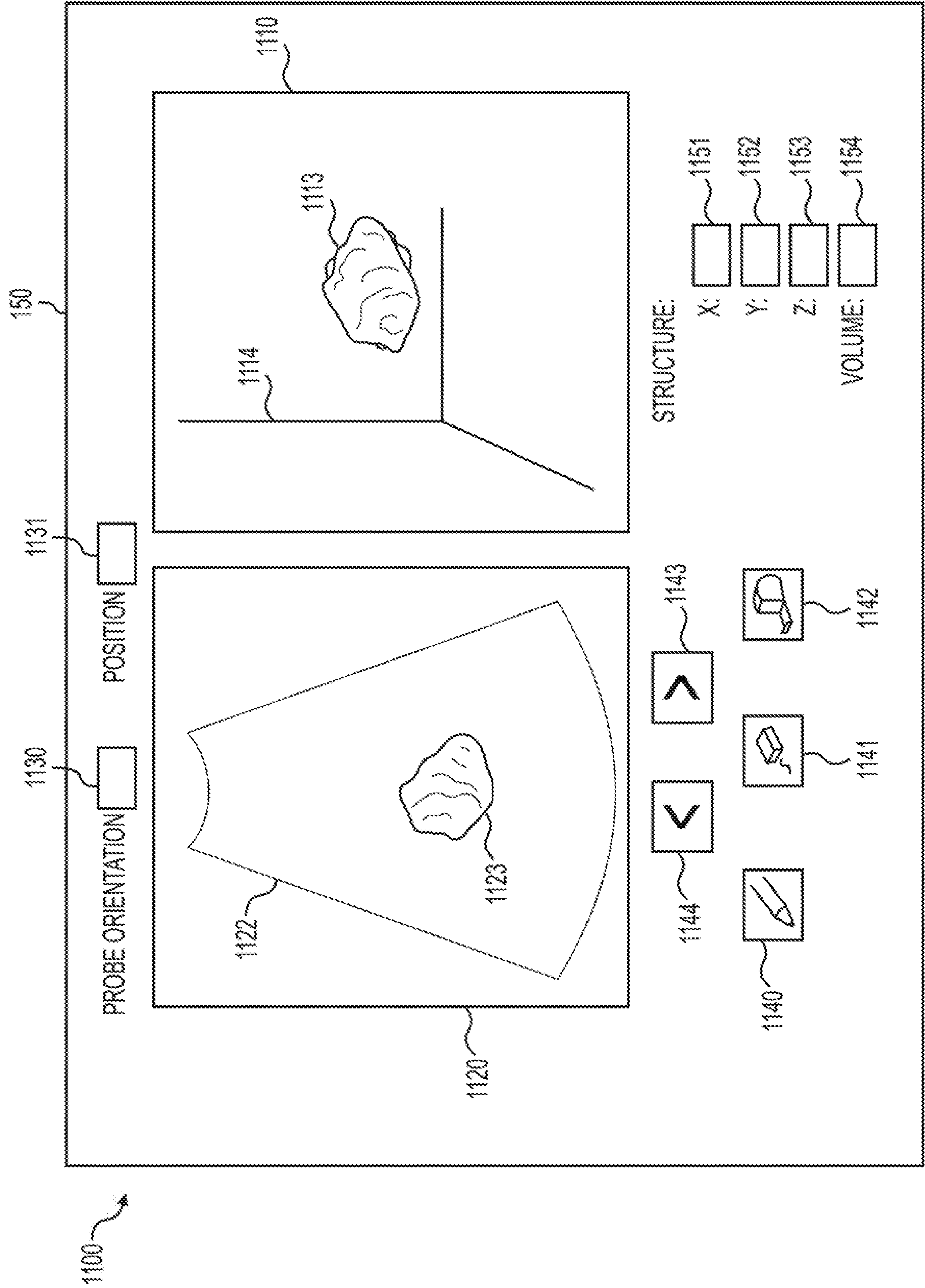


FIG. 11

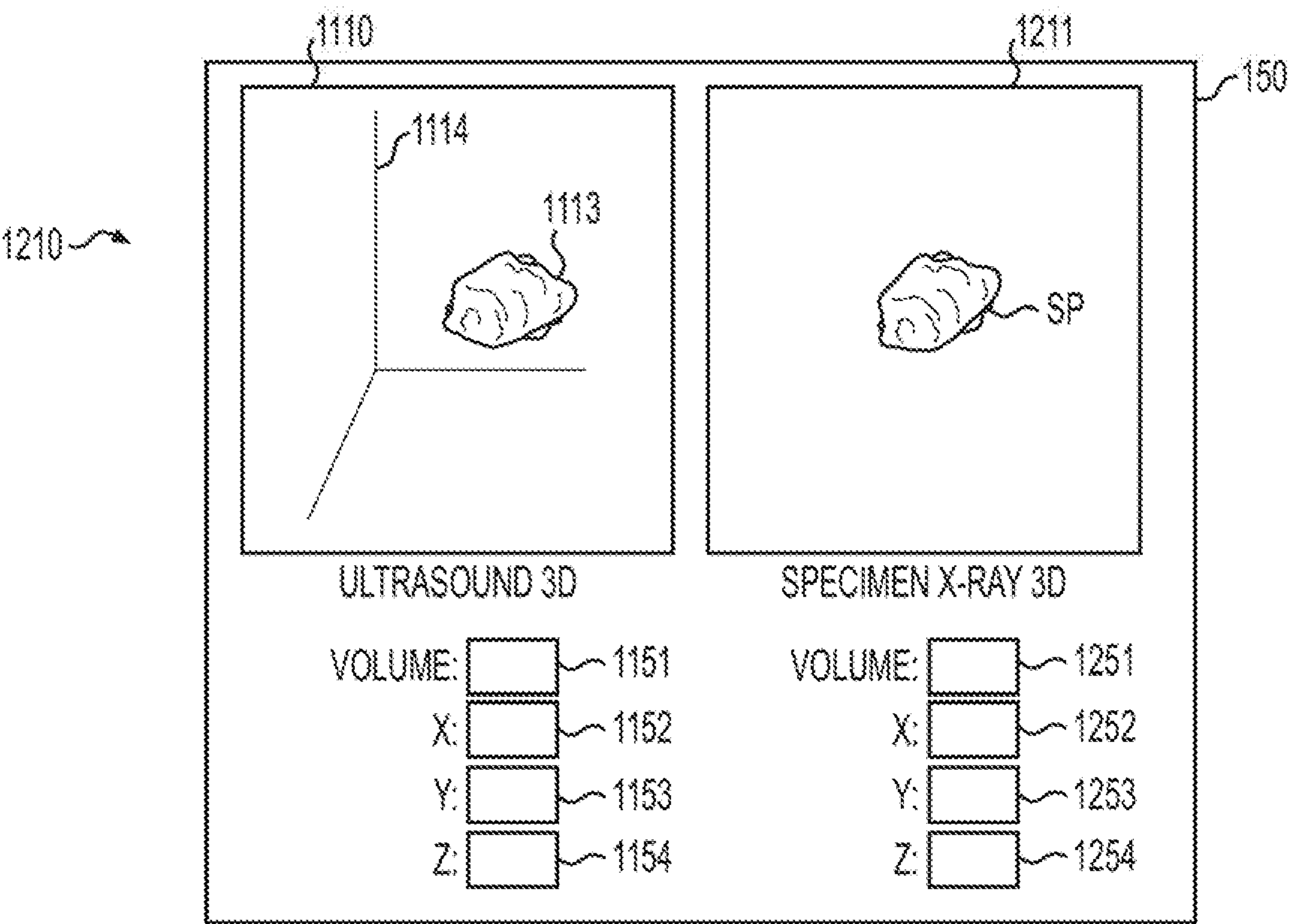


FIG. 12A

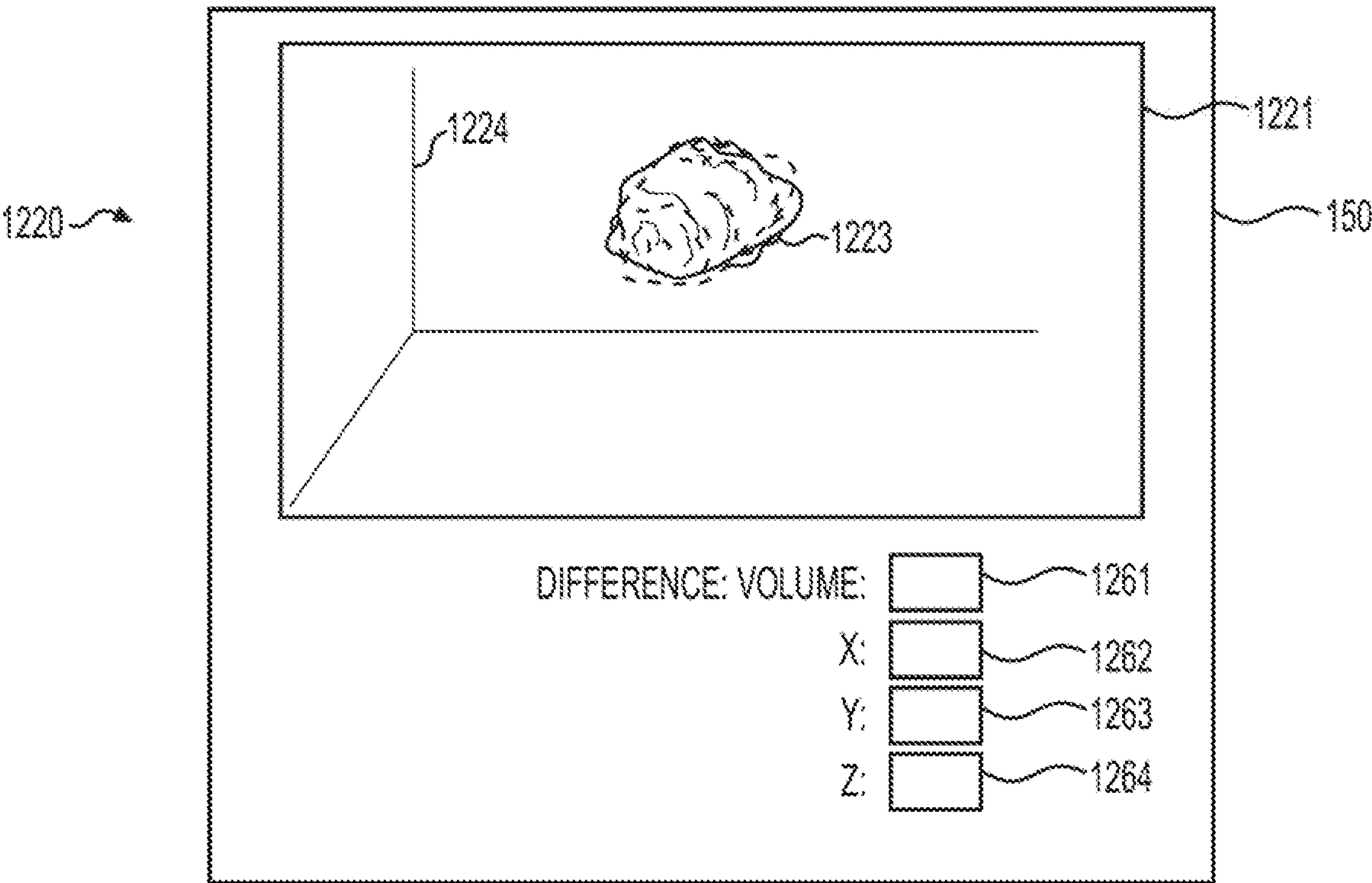


FIG. 12B

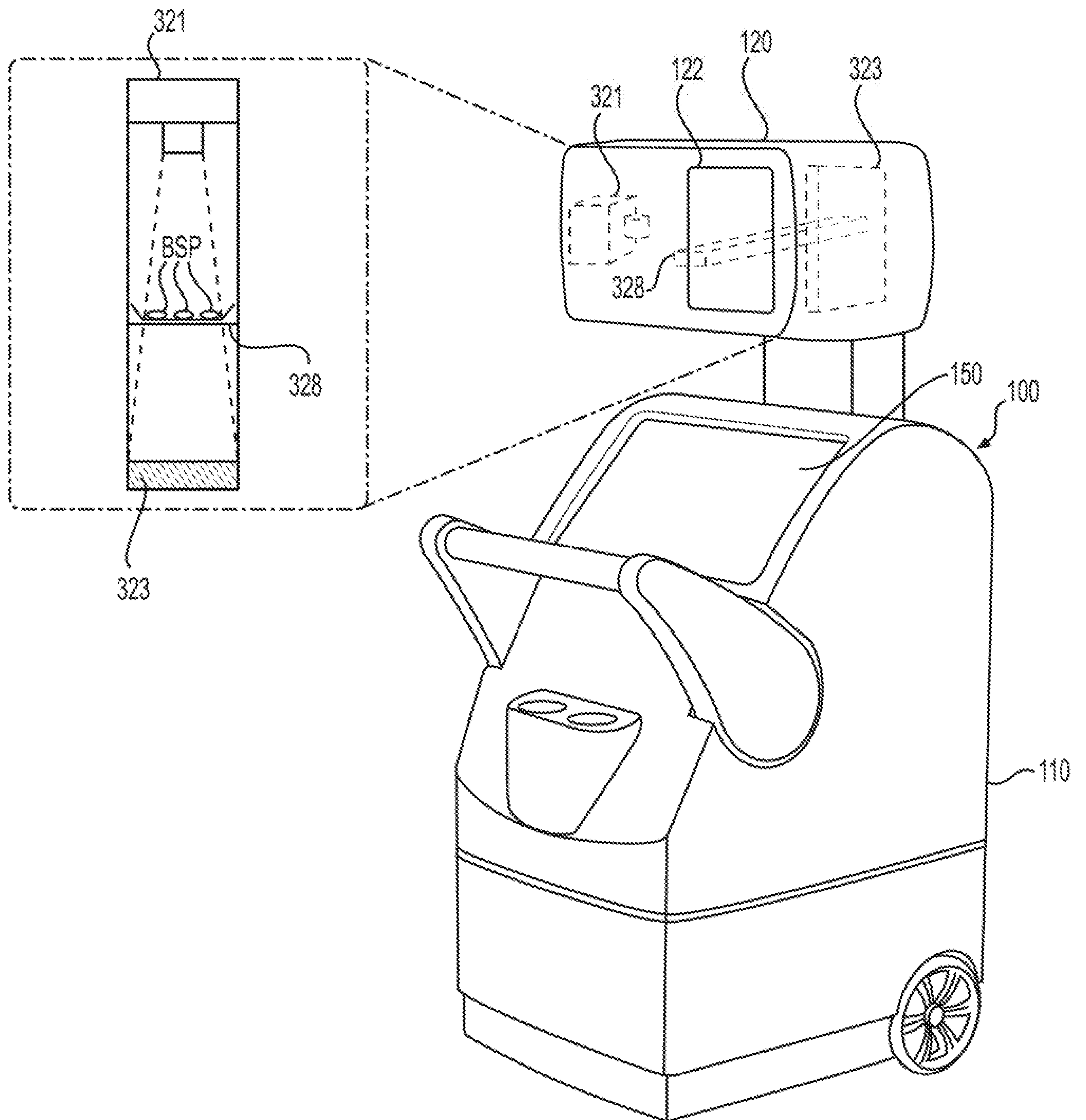
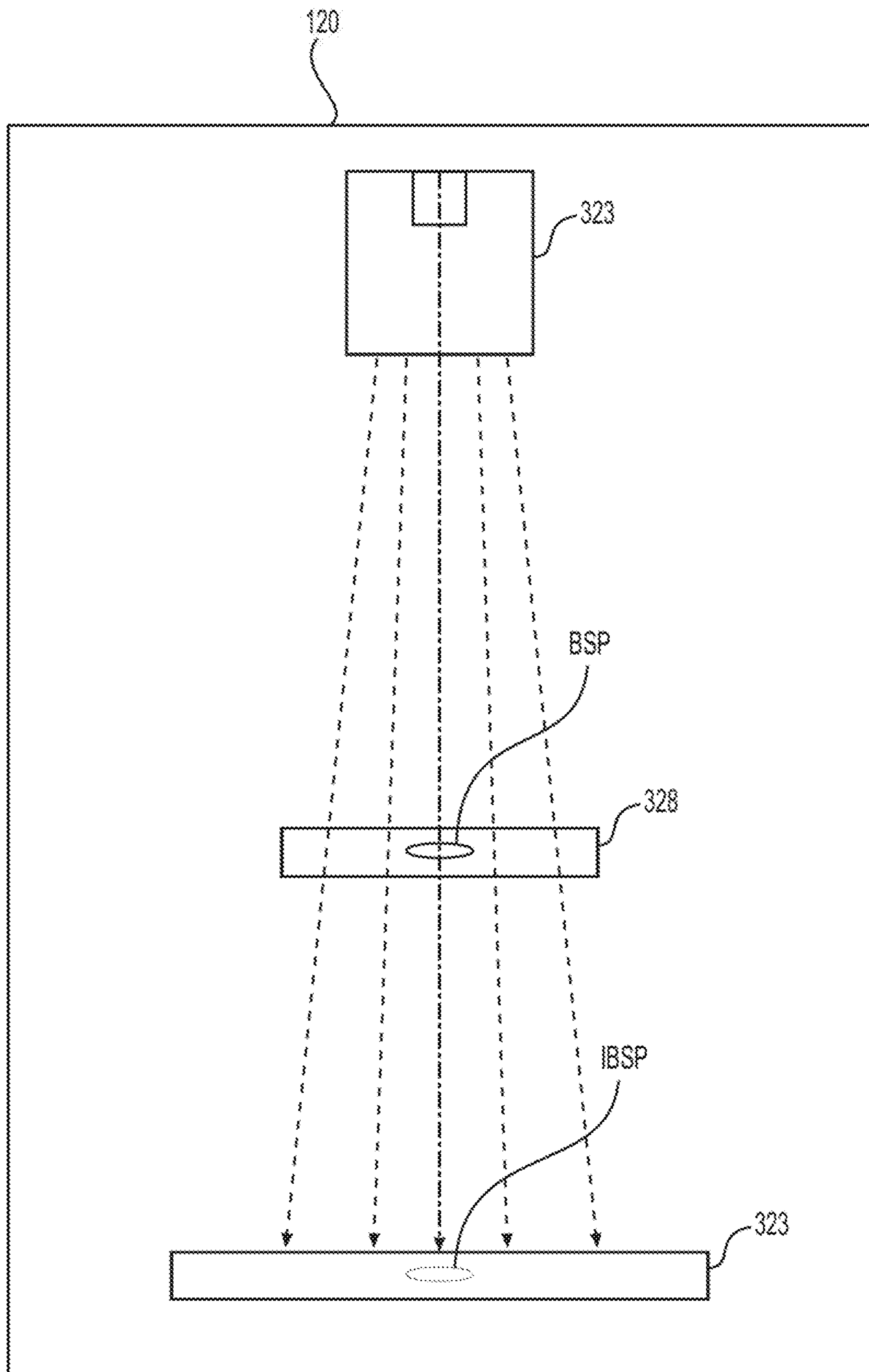
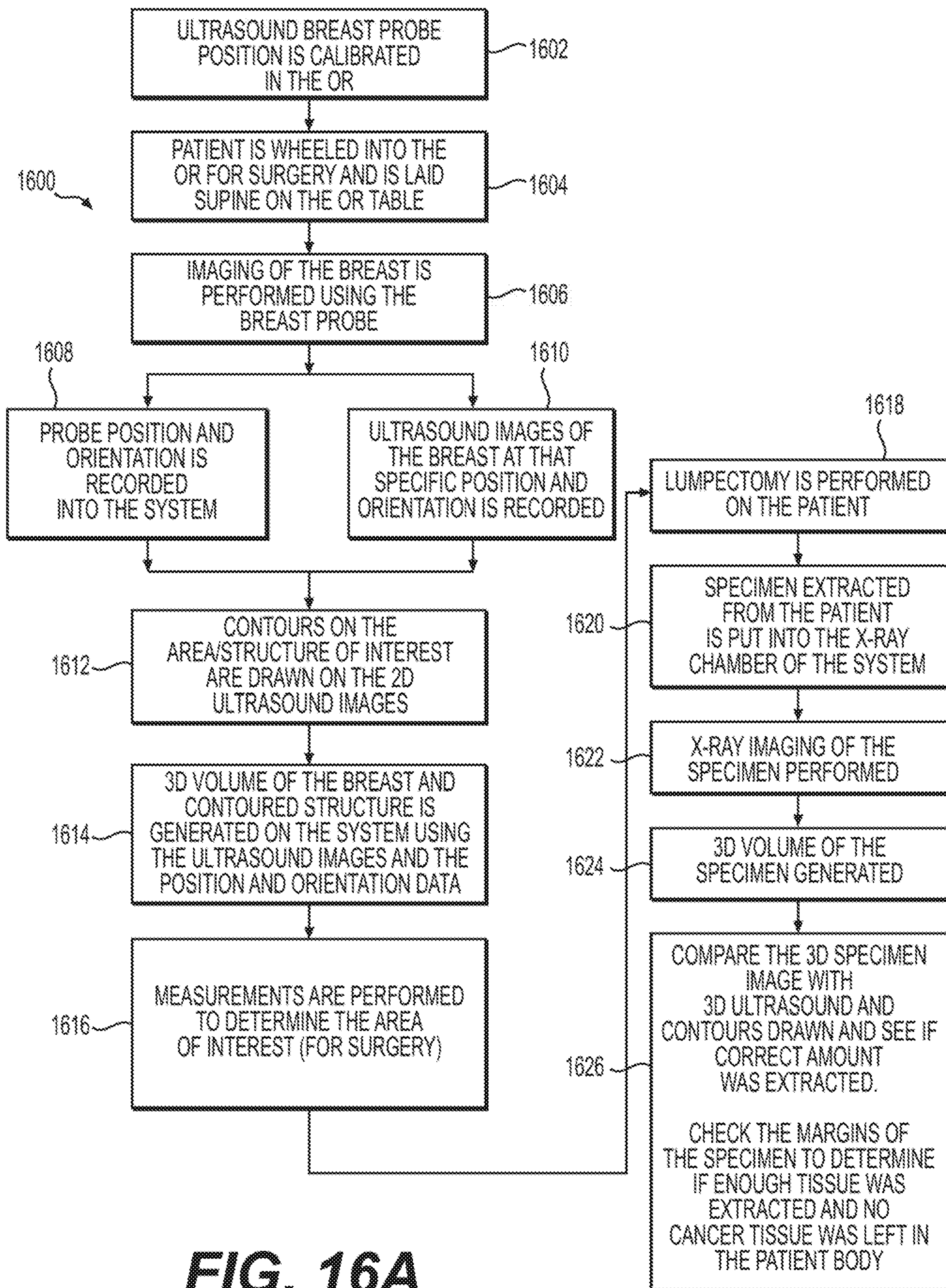
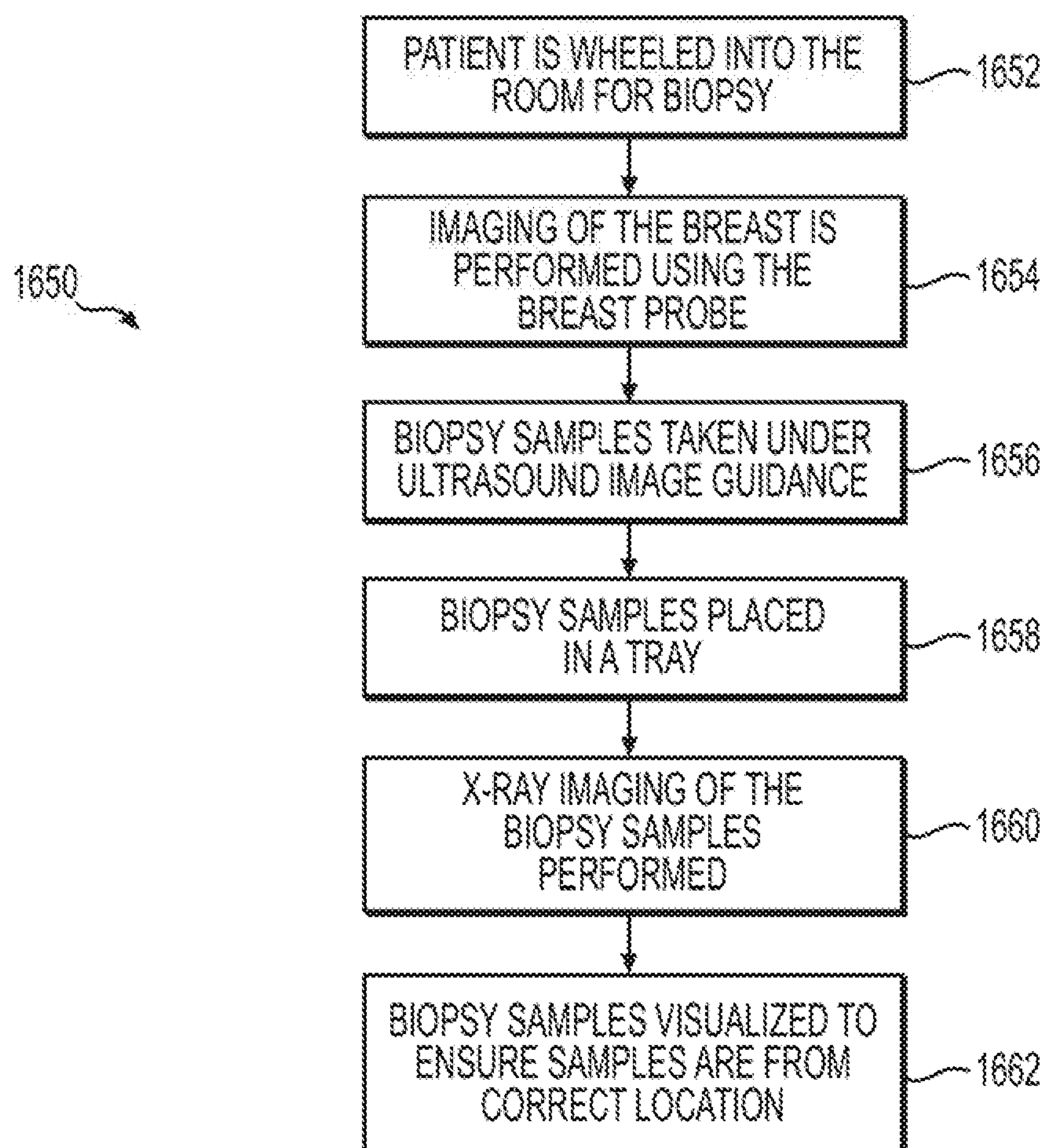


FIG. 13

**FIG. 14**

**FIG. 16A**

**FIG. 16B**

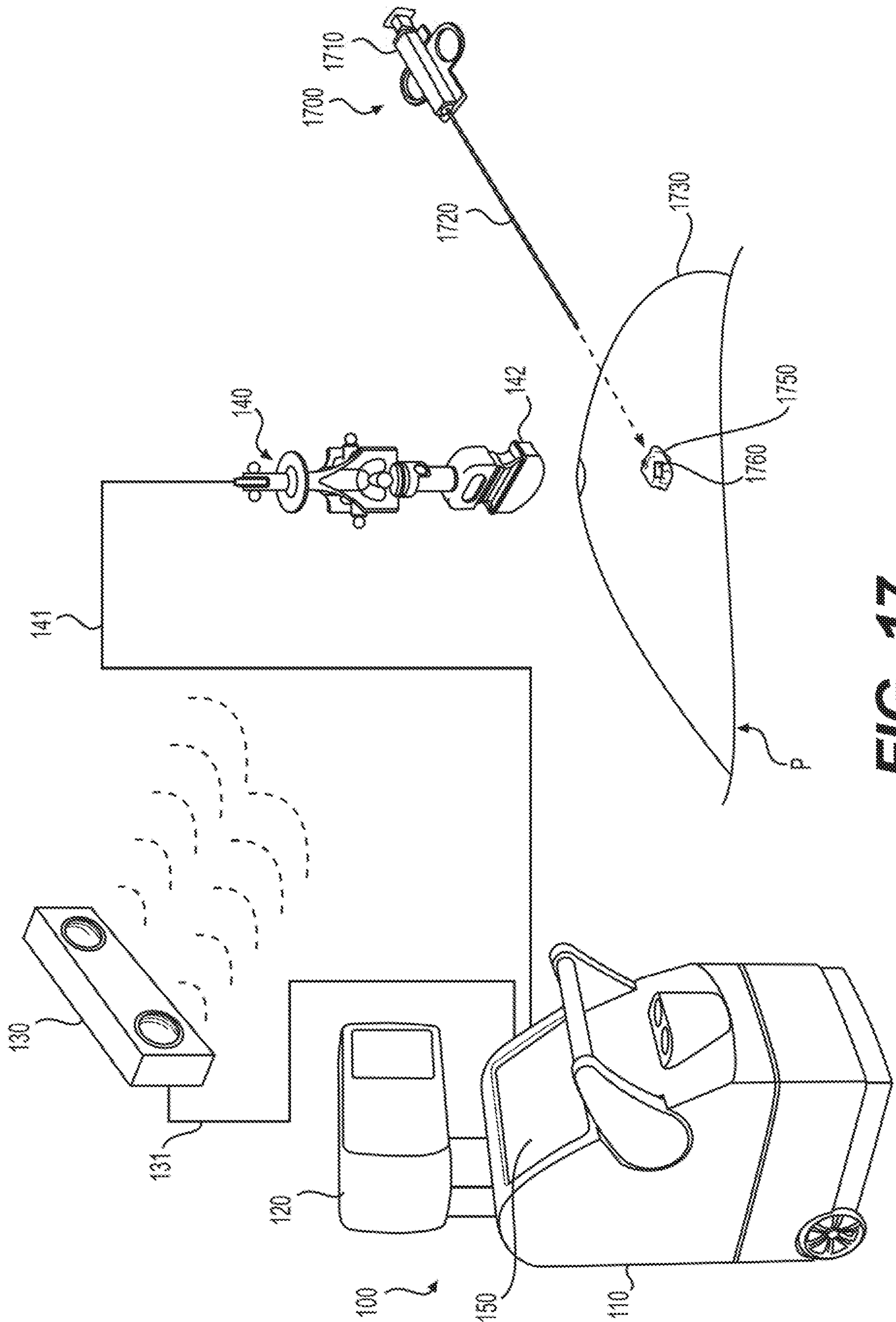


FIG. 17

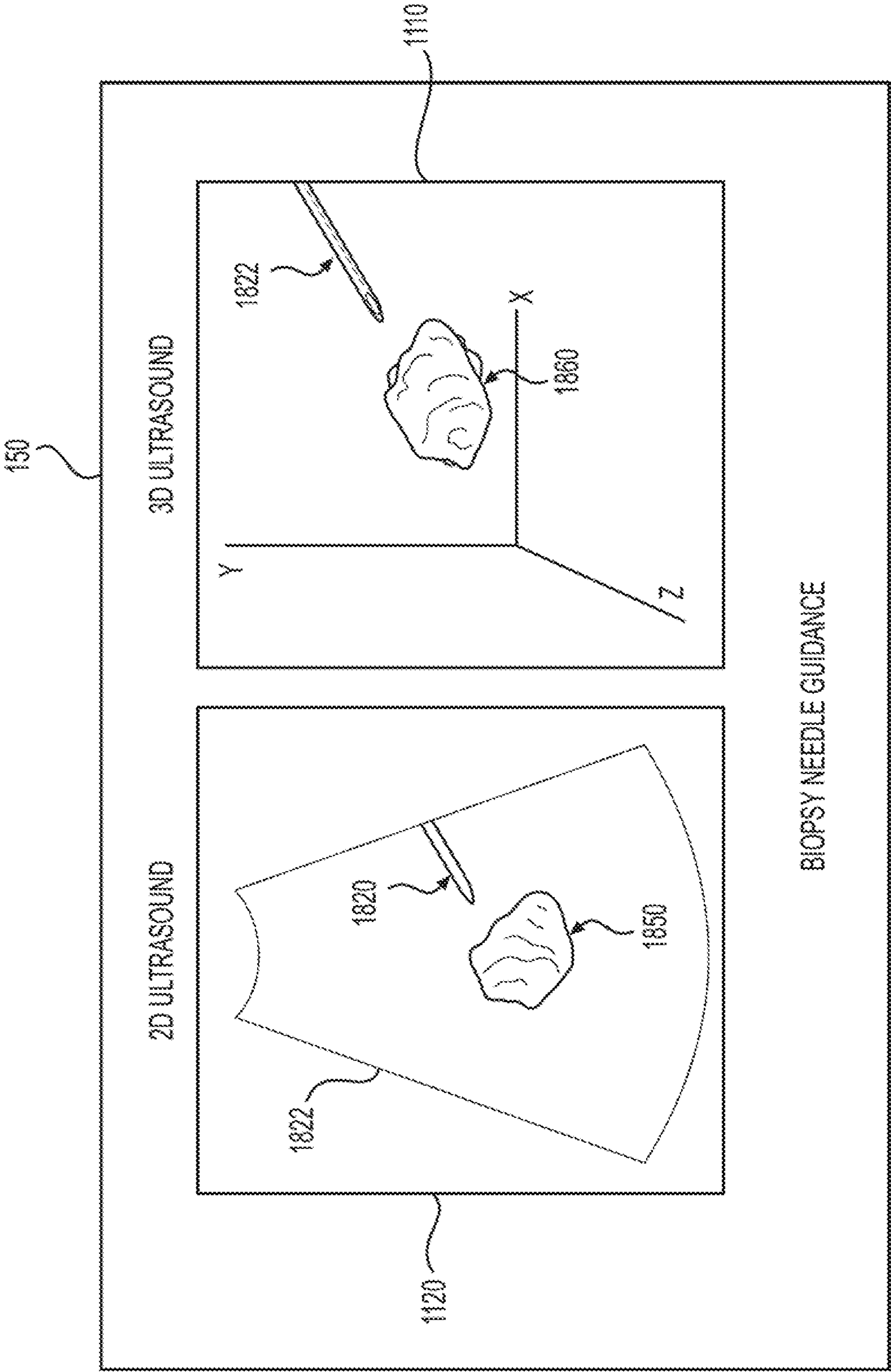


FIG. 18A

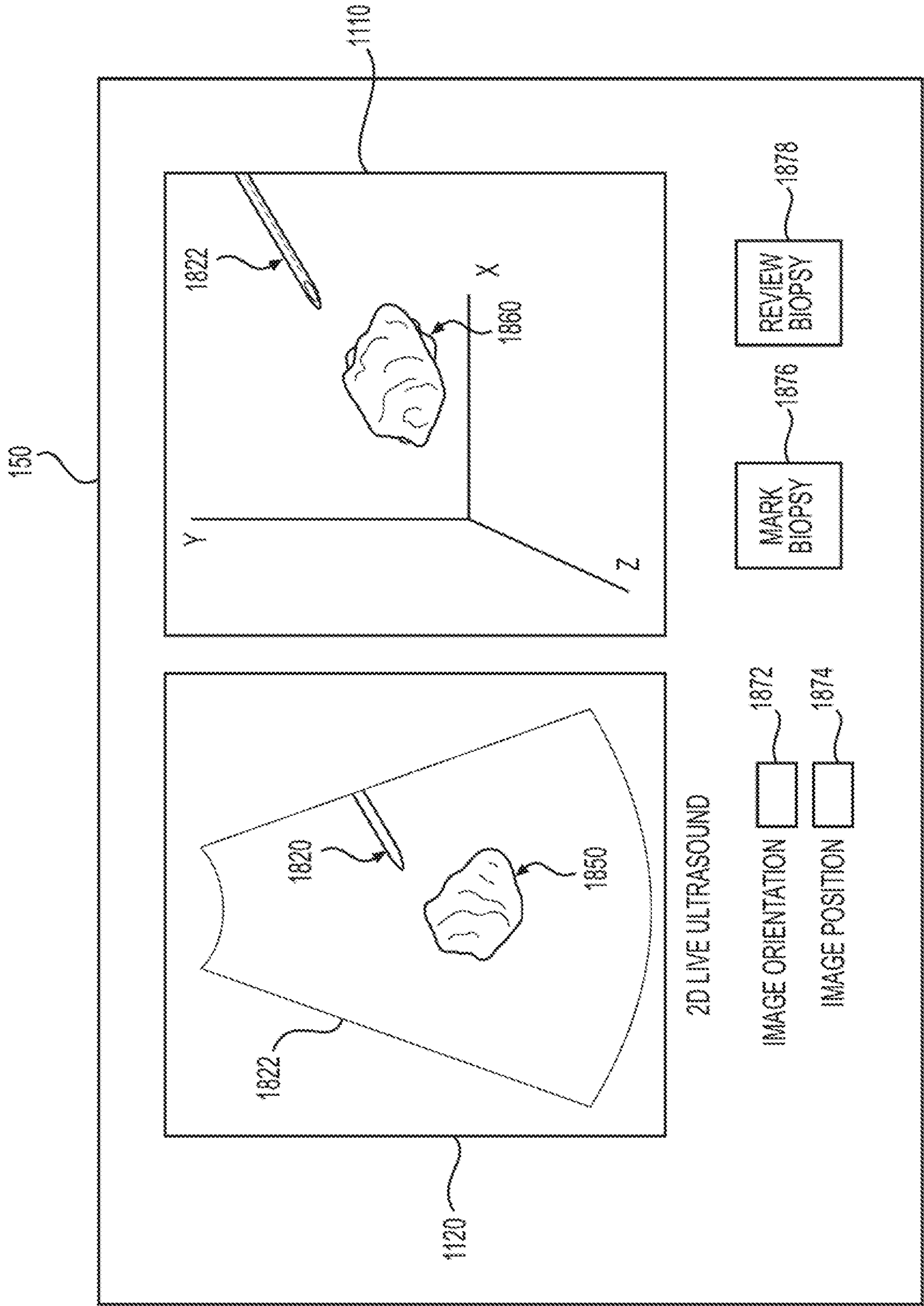
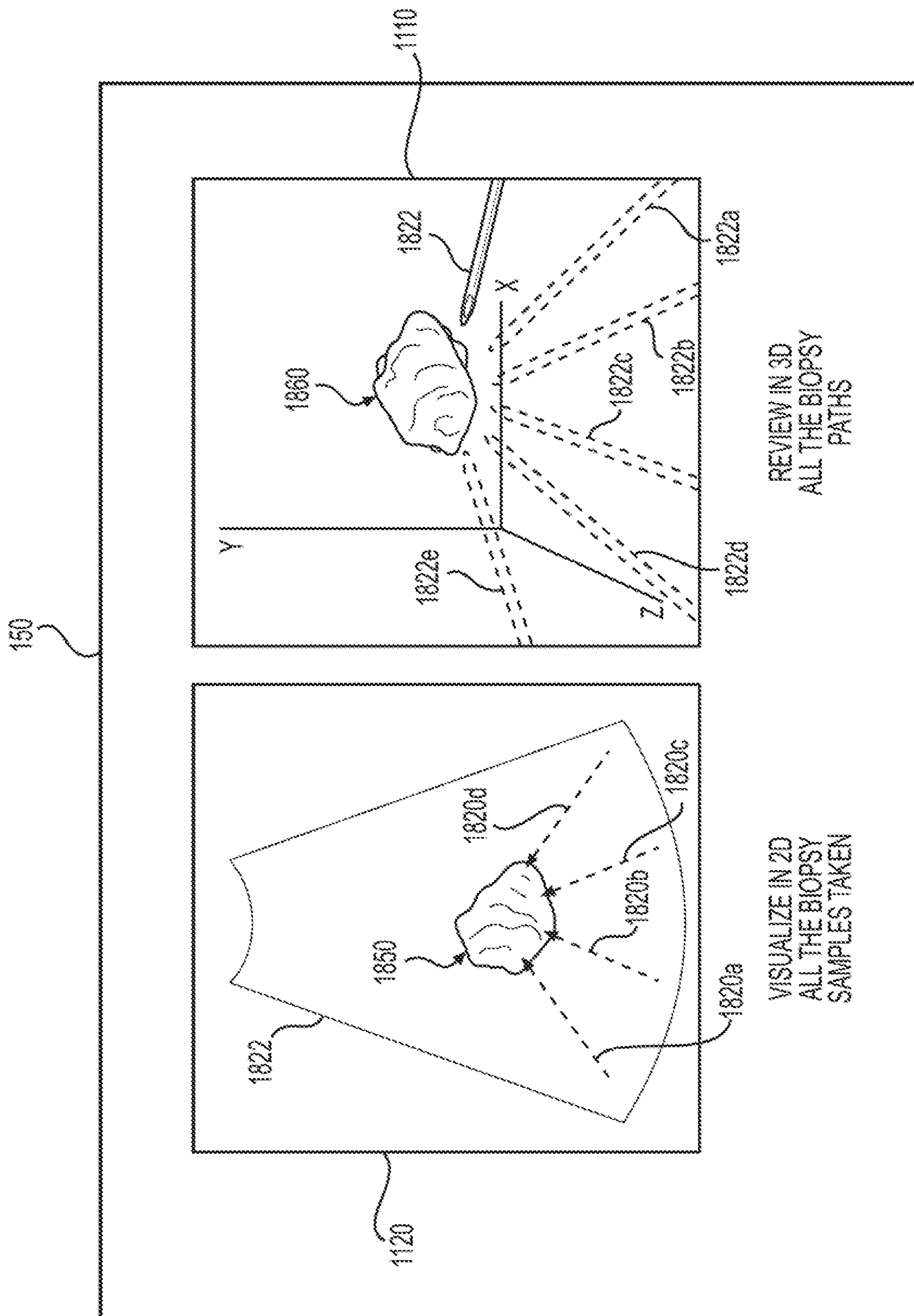
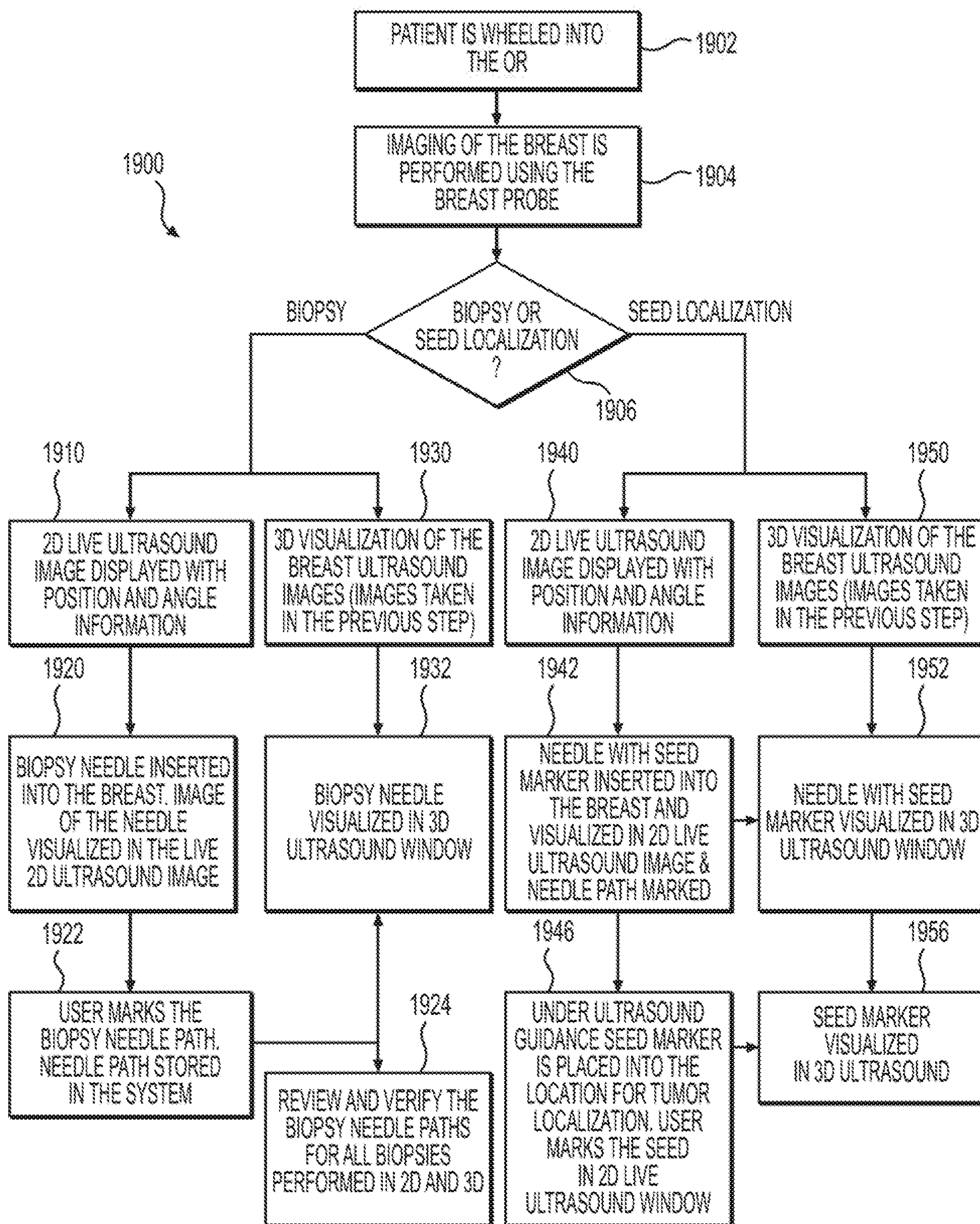


FIG. 18B

**FIG. 18C**



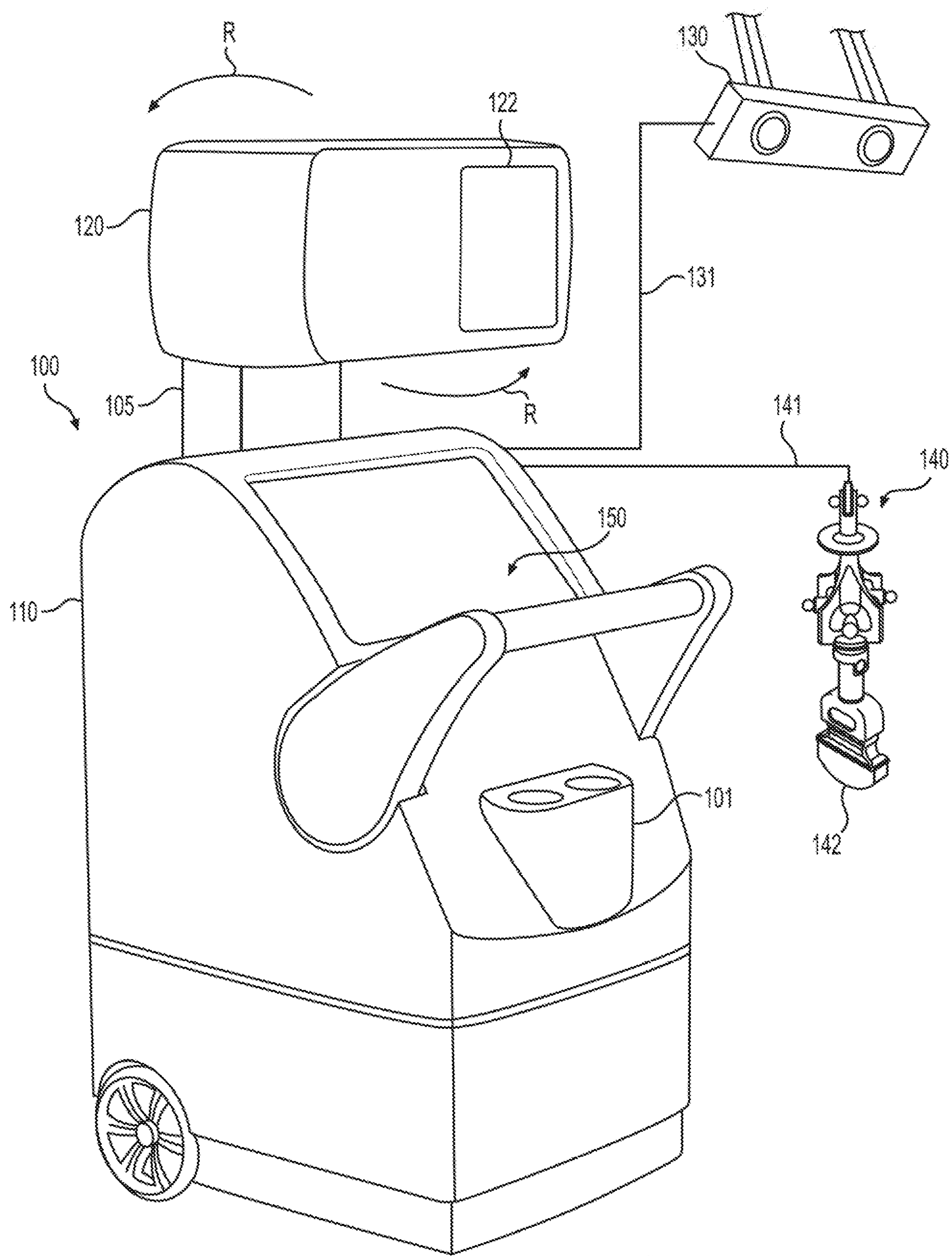


FIG. 1A